**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF RHODE ISLAND**

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| IN RE: LOESTRIN 24 FE ANTITRUST LITIGATION | MDL No. 2472<br><br>Master File No. 13-md-2472-WES-PAS |
| THIS DOCUMENT RELATES TO: ALL ACTIONS | **FILED UNDER SEAL** |

**MEMORANDUM IN SUPPORT OF**
**PURCHASERS' OMNIBUS MOTION *IN LIMINE***

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*I*

This Memorandum in Support of Purchasers' Omnibus Motion *in Limine* is filed on behalf of all Purchasers, including the Direct Purchasers, Retailers, and End-Payors (collectively, "Purchasers").

## I. MOTIONS RELATED TO MISCELLANEOUS TRIAL ISSUES

### A. Motion No. 1: Purchasers' Motion *in Limine* to Preclude Evidence or Statements Regarding Pass On, Lost Profits, or Generic Bypass

This Court has already held that "purchasers are injured at the point in time they incur the overcharge," such that they may recover the "full amount of overcharges."[1] Consistent with that holding, Purchasers move to preclude Defendants' witnesses and counsel from offering any evidence or argument that (1) "lost profits" would be a more appropriate measure of damages, (2) Purchasers' damages or injury could be diminished by any evidence of Purchasers "passing on" an overcharge to their customers, or (3) that Purchasers' damages should be reduced to account for so-called "generic bypass."

Purchasers have already filed a motion to exclude evidence and argument from Defendants' expert Dr. Cremieux on these grounds.[2] That motion is pending before the Court. This motion renews the pending motion as to Dr. Cremieux, but it also expands the motion to ensure that lay witnesses and Defendants' counsel do not testify to, or provide argument about, these issues. Purchasers thus incorporate by reference the arguments and authorities in the pending motion as to Dr. Cremieux.

First, Defendants' witnesses should not be allowed to testify about whether Purchasers profited (or not) from Defendants' illegal conduct. "The Supreme Court has 'long recognized

[1] Op. & Order, July 2, 2019, ECF No. 1050 at 13 n.10.

[2] Pls.' Mot. to Exclude Portions of Testimony of Defs.' Expert Dr. Pierre Yves-Cremieux, May 17, 2019, ECF No. 868.

[overcharges] as the principal measure of damages for plaintiffs injured as customers.'"[3] Here, Purchasers were overcharged each time they either (1) purchased brand Loestrin and/or Minastrin but would have purchased cheaper generic Loestrin but for Defendants' unlawful impairment of generic competition, or (2) purchased generic Loestrin 24 that would have been cheaper but for the unlawful impairment of generic competition. Every court addressing this issue has held that direct purchasers alleging unlawfully impaired generic competition are entitled to seek overcharges.[4] Defendants should therefore not be permitted to "go beyond the fact of th[e] [overcharge] injury to determine whether the victim of the overcharge has partially recouped its loss in some other way," [5] whether through passing on an overcharge, recouping lost profits, or changing purchasing patterns through "generic bypass."

Second, Defendants should be precluded from offering any evidence or argument—either through lay or expert witnesses—that Purchasers "passed on" any overcharges in the form of higher prices to indirect purchasers. An "antitrust defendant is not permitted to introduce evidence that indirect purchasers were in fact injured by the illegal overcharge."[6] The Supreme Court upheld the rule of *Illinois Brick* just this term in *Apple Inc. v. Pepper*, 139 S. Ct. 1514, 1519 (2019).[7] In direct purchaser antirust cases, courts routinely grant motions *in limine* to bar introduction of pass-

[3] Op. & Order, ECF No. 1050 at 14 n. 10 (quoting *In re Nexium (Esomeprazole) Antitrust Litig.*, 296 F.R.D. 47, 55 (D. Mass. 2013)).

[4] *See* Mem. of Law in Support of Pls.' Mot. to Exclude Portions of Test. of Defs.' Expert Dr. Pierre-Yves Cremieux, May 17, 2019, ECF No. 868-2 at 4 n.6 (collecting cases).

[5] *Hawaii v. Standard Oil Co. of Cal.*, 405 U.S. 251, 262 n.14 (1972).

[6] *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 724-25 (1977).

[7] The law is equally clear that indirect purchasers can recover under state laws for any overcharges that they sustain, as a result of *California v. ARC America Corp.*, 490 U.S. 93 (1989) and its progeny.

on evidence.[8] For the same reason, Defendants should be barred from making any argument that the Direct Purchasers or Retailers somehow profited from the overcharge.[9]

Third, the Court should likewise preclude Defendants from making any reference to "generic bypass," in which wholesalers may sell higher volumes of branded than generic drugs because some of the wholesalers' customers may purchase generic drugs directly from manufacturers (thereby "bypassing" the wholesaler). Courts, including this Court at class certification,[10] have uniformly held that such evidence is irrelevant to the only appropriate measure of damages: the overcharge caused by Defendants' anticompetitive conduct.[11]

For the foregoing reasons, Purchasers respectfully request that the Court bar Defendants' counsel and witnesses from offering evidence or argument (1) about how "lost profits" would be a more appropriate measure of damages, (2) that Purchasers' damages or injury could be diminished by any evidence of Purchasers "passing on" an overcharge to their customers, or (3) that Purchasers' damages should be reduced to account for so-called "generic bypass."

### B. Motion No. 2: Purchasers' Motion *in Limine* to Preclude Defendants From Challenging the Validity of Direct Purchasers' or Retailers Assignments in the Liability Trial

[8] *See, e.g., In re Lidoderm Antitrust Litig.*, No. 14-md-02521, 2018 WL 7814761, at *3 (N.D. Cal. Feb. 7, 2018) ("Defendants may not solicit or introduce evidence solely for the purpose of showing that DPPs pass-on damages or that DPP damages should be reduced."); *Gulfstream III Assocs., Inc. v. Gulfstream Aerospace Corp.*, 995 F.2d 425, 432 (3d Cir. 1993) (affirming exclusion of downstream evidence because it is "irrelevant and inadmissible for the purpose of showing that plaintiff did not suffer the full amount of the alleged overcharge").

[9] *See, e.g., In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 369 (D. Mass. 2004) ("*Hanover Shoe* permits a direct purchaser to recover the 'full amount of the overcharge,' even if he is otherwise benefited" (citations omitted)); *In re Nexium (Esomeprazole) Antitrust Litig.*, 296 F.R.D. 47, 56 (D. Mass. 2013).

[10] Op. & Order, ECF No. 1050 at 13 n.10.

[11] *In re Relafen*, 346 F. Supp. 2d at 368-69; *see also In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d. 231, 297 (D. Mass. 2014) (holding in reliance on *Relafen* that "generic bypass cannot be a defense that precludes the Plaintiffs from recovering damages based on overcharge calculations"); *In re Niaspan Antitrust Litig.*, No. 13-md-2460, 2015 WL 4197590, at *1-2 (E.D. Pa. July 9, 2015) (collecting cases).

Retailers and Direct Purchaser Ahold U.S.A., Inc. ("Ahold") respectfully request a ruling that the validity of their assignments from pharmaceutical wholesalers will be litigated, if at all, during the damages phase of the trial. Purchasers' assignments are legal instruments whose interpretation and validity are issues of law rather than issues of fact, and the Court should rule on any challenge to their validity.[12] Purchasers have been litigating their assigned claims in this Court for six years, and Defendants have never raised any challenge to the validity of the assignments, legal or factual. To the extent that Defendants raise any belated challenges that create triable issues of fact, those challenges should be litigated during the damages phase of the trial. The assignments are relevant only to Purchasers' standing to recover overcharge damages, not to their standing to pursue antitrust claims.[13]

Each of the Retailers and Ahold holds one or more express and presumptively valid assignments from a pharmaceutical wholesaler that allow them to stand in the wholesaler's shoes with respect to Loestrin 24 (and in some cases Minastrin 24 and generic Loestrin 24) purchased by the wholesaler and resold to them. Such assignments are common in pharmaceutical cases.[14] In the six years these cases have been pending, Defendants have never given the Court any reason to question the validity of these assignments, and it is doubtful that they have standing to do so.[15]

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[12] *See Wallach v. Eaton Corp.*, 837 F.3d 356, 371 (3d Cir. 2016) (antitrust assignments that were express and in writing were valid as a matter of federal common law).

[13] *See Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 111 n.6 (1986); *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 401 (3d Cir. 2000); *Int'l Ass'n of Machinists & Aerospace Workers, AFL-CIO, Local Lodge No. 1821 v. Verso Paper Corp.*, 80 F. Supp. 3d 247, 271 (D. Me. 2015).

[14] *See, e.g.*, *In re Loestrin 24 Antitrust Litig.*, No. 13-md-2472, 2019 WL 3214257, at *11-12 (D.R.I. July 2, 2019) (rejecting argument that Ahold's status as a partial assignee made it an atypical class member); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 309 F.R.D. 195, 205 (E.D. Pa. 2015) (assignments to class representatives were "valid and . . . allow[ed] [the class representatives] to pursue claims for the alleged antitrust violations").

[15] *See In re Circle K Corp.*, 127 F.3d 904, 908 (9th Cir. 1997) (rejecting challenge by third party to validity of assignments: "The parties to the assignments do not challenge their validity; it would be for them, not Coleman, to raise the statute of frauds as a defense . . . ."); *Dixon v. Stern & Eisenberg, PC*, No. 14-cv-4551, 2015 WL 3833782,

Even if Defendants had standing, Purchasers' assignments are legal instruments whose interpretation and validity raise issues of law for the Court, not issues of fact for the jury. Antitrust assignments are governed by federal common law.[16] Applying federal common law, the Southern District of New York noted the following in the *DNAML* case:

> Courts of Appeals have fashioned a uniform rule for the assignment of a federal antitrust claim. To effect a transfer of the right to bring an antitrust claim, the transfer[or] must expressly assign the right to bring that cause of action, either by making specific reference to the antitrust claim or by making an unambiguous assignment of causes of action in a manner that would clearly encompass the antitrust claim.[17]

There can be no dispute that Purchasers' assignments satisfy this requirement on their face: they expressly transfer the right to bring antitrust claims from the wholesaler to the wholesaler's customer. Thus, Purchasers' assignments are valid as a matter of law, and there is nothing for a jury to decide.[18]

Finally, to the extent that Defendants raise any last-minute factual challenges to Purchasers' assignments, those challenges should be litigated during the damages phase of the trial, not the liability phase. There is no dispute that Retailers are part of the pharmaceutical distribution chain. That is sufficient to give them standing to pursue a liability verdict.[19]

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at *11 (E.D. Pa. June 22, 2015) (plaintiff lacked standing to challenge validity of mortgage assignment between defendant and third party).

[16] *See Wallach*, 837 F.3d at 366 (in deciding validity of antitrust assignment not supported by consideration, "we must apply federal common law, as opposed to the law of the state"); *Gulfstream III Assocs., Inc.*, 995 F.2d at 437 ("[T]he validity of the assignment of an antitrust claim is a matter of federal common law."); *DNAML Pty, Ltd. v. Apple Inc.*, No. 13-cv-6516, 2015 WL 9077075, at *3 (S.D.N.Y. Dec. 16, 2015) (assignability of federal antitrust claims and legal rules governing such assignments are matters of federal law).

[17] *DNAML Pty, Ltd.*, 2015 WL 9077075 at *3.

[18] *See Wallach*, 837 F.3d at 371 (antitrust assignments that were in writing and express were valid as a matter of law); *In re Circle K Corp.*, 127 F.3d at 908 (validity of assignments was properly determined as a matter of law).

[19] *See Cargill*, 479 U.S. at 111 n.6; *In re Warfarin*, 214 F.3d at 401; *Int'l Ass'n of Machinists*, 80 F. Supp. 3d at 271.

Recognizing as much, Judge Young entered a similar order precluding litigation of the validity of the plaintiffs' assignments during the liability phase of the *Nexium* case.[20]

For the foregoing reasons, Retailers and Direct Purchaser Ahold respectfully request a ruling that the validity of their assignments from pharmaceutical wholesalers will be litigated, if at all, during the damages phase of the trial.

### C. Motion No. 3: Direct Purchasers' Motion *in Limine* to Bar Arguments or Evidence That the Direct Purchaser Class Includes Three Large Absent Class Members

Defendants may seek to introduce argument or evidence that Direct Purchasers include three absent class members that are relatively large as compared to the rest of the members of the Direct Purchasers. This fact is plainly irrelevant given the Court's order certifying the Direct Purchaser Class and finding the class representatives adequate under Rule 23(a)(4), and is prejudicial because it would be offered to somehow cast doubt on the propriety of this action. .[21] In a similar pay-for-delay case, the *Lidoderm* court recently held, for example, that "[a]t trial, defendants may not argue that class certification is inappropriate or otherwise not warranted on the facts of this case. Similarly, at trial defendants may not argue that aggregate damages are not

[20] *See In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-2409, ECF No. 1064 (D. Mass. Oct. 16, 2014).

[21] Furthermore, any mention of other past or present civil or criminal litigation or settlements with private parties or governmental entities that may involve absent class members, including any mention of their alleged sale or distribution of opioid drugs, should be excluded on grounds of irrelevance and unfair prejudice under Federal Rules of Evidence 401-403. Order, *In re Lidoderm Antitrust Litig.*, No. 3:14-md-02521-WHO (N.D. Cal. Feb. 7, 2018), ECF No. 978 at 9 (barring comment on "other litigation" involving plaintiffs); *Eng v. Scully*, 146 F.R.D. 74, 79 (S.D.N.Y. 1993) (evidence of plaintiff's prior litigation inadmissible as irrelevant under Federal Rules of Evidence 401 and 402).

warranted as a legal matter."[22] In other similar cases, even the defendants agreed not to raise the issue.[23]

### D. Motion No. 4: End-Payors' Motion *in Limine* to Exclude Reference to Direct Purchaser Recoveries in the Separate End-Payor Damages Phase

End Payors request that the Court preclude from the End Payor damages phase of the trial any testimony or argument concerning Direct Purchasers' or Retailers' actual or potential damages or recoveries. The Supreme Court has recognized that there is no "federal policy against *States* imposing liability *in addition to* that imposed by federal law."[24] Moreover, courts in this Circuit and elsewhere have repeatedly held that, when direct purchasers bring federal law claims and indirect purchasers bring state law claims, duplicative recoveries are permissible.[25] As the court in *Asacol* explained, states that allow "indirect purchasers to sue for antitrust violations[] have necessarily made the policy decision that duplicative recovery may permissibly occur."[26] Accordingly, duplicative recovery is "a necessary consequence that flows from indirect purchaser recovery."[27]

Consistent with this Court's bifurcation order, evidence of Direct Purchasers' or Retailers' recoveries has no probative value in a trial to determine End Payors' damages. Moreover, the

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[22] *In re Lidoderm Antitrust Litig.*, Moti. for Recons. re Proof to Establish Causation, Feb. 7, 2018, No. 14-02521, ECF No. 978 at 5.

[23] *See, e.g.*, *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-2503-DJC, ECF No. 1089 (D. Mass. Mar. 8, 2018).

[24] *ARC Am. Corp.*, 490 U.S. at 105 (emphasis added).

[25] *E.g.*, *In re Asacol Antitrust Litig*., No. 15-cv-12730, 2017 WL 53695, at *3 (D. Mass. Jan. 4, 2017); *In re Propranolol Antitrust Litig.*, 249 F. Supp. 3d 712, 726 (S.D.N.Y. 2017); *In re Lithium Ion Batteries Antitrust Litig.*, No. 13-md-2420, 2014 WL 4955377, at *16 n.16 (N.D. Cal. Oct. 2, 2014); *In re Auto. Parts Antitrust Litig.*, No. 12-md-02311, 2013 WL 2456612, at *18 (E.D. Mich. June 6, 2013); *In re Ductile Iron Pipe Fittings (DIPF) Indirect Purchaser Antitrust Litig.*, No. 12-cv-169, 2013 WL 5503308, at *18 (D.N.J. Oct. 2, 2013); *In re Flash Memory Antitrust Litig.*, 643 F. Supp. 2d 1133, 1156 (N.D. Cal. 2009).

[26] *In re Asacol*, 2017 WL 53695, at *3 (quoting *In re Flash Memory*, 643 F. Supp. 2d at 1156).

[27] *Id.*

introduction of such evidence would prejudice End Payors because it could confuse the jury and incorrectly cause it to reduce End Payors' damages in light of potential damages or a recovery by Direct Purchasers or Retailers.[28] For these reasons, this Court should preclude from the End Payor damages phase any testimony or argument concerning Direct Purchasers' or Retailers' actual or potential damages or recoveries.

### E. Motion No. 5: Purchasers' Motion *in Limine* to Exclude Argument or Testimony Concerning Purported Pass-on of Overcharges by End-Payors

Purchasers move to preclude Defendants from offering evidence or argument that overcharges related to Loestrin 24 and Minastrin 24 purchases by class members were somehow "passed on" in the form of higher insurance premiums or contributions. Such assertions, in addition to being false and unsupportable, are entirely irrelevant to the claims and defenses in this action, and therefore would confuse and mislead the jury. Accordingly, Defendants should be prohibited from introducing these arguments under Federal Rules of Evidence 402 and 403.

There are several reasons for precluding any evidence and arguments of End Payor pass-on. *First*, End Payors are pursuing claims on behalf of a class of end-payors, defined in part as "All Third-Party Payor entities . . . who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Loestrin 24 Fe and/or . . . Minastrin 24 Fe . . . *other than for resale* . . . ."[29] In short, "End-Payors" are simply that: the last payers in the chain of distribution for Loestrin 24 and Minastrin 24. TPPs and insured consumers each share and pay their part of the price for Loestrin 24 and Minastrin 24. TPPs reimburse for the Loestrin 24 and Minastrin 24

[28] Fed. R. Evid. 403.

[29] End-Payor Pls.' Reply Mem. of Law in Further Support of Their Motion for Class Certification & Appointment of Class Counsel, Dec. 7, 2018, ECF No. 633 at 6 (emphasis added).

used by their insureds, and pay the price of the product minus the co-payment or co-insurance, if any, paid by the insured. TPPs do not pass on their portion of the overcharge.

*Second*, insurance premiums set by TPPs are not a pass-on of incurred costs. To the contrary, TPPs do not seek to "recoup" anything through premiums. When a prescription is filled, the TPP becomes obligated to pay its portion of the prescription cost. The premium applicable to the policy requiring the payment was set before the charge was ever incurred. In other words, premiums and plan contributions are forward-looking—i.e., they are based on an estimate of future plan costs, not an attempt to recoup or offset past payments.[30] Moreover, premiums are set using *aggregate* information on multiple drugs for multiple insureds to predict *aggregate* future claims. There is no evidence they are calculated based on the cost of any one drug.[31]

*Third*, the named class representatives in the current litigation are self-funded plans. By definition, these plans do not set premiums. In self-funded plans, the plan sponsor assumes the direct risk for payment of the claims for benefits. The plans negotiate contribution rates with the applicable union and deposit their funds into a trust from which medical benefits are paid. The contribution rates are set by contracts that can span a number of years and, like premiums, are

[30] *In re Asacol*, 2017 WL 53695, at *4 ("[I]nsurance premiums are not a 'pass on' of alleged overcharges because premiums are set by anticipating future projected costs, not to recover money that insurers paid in the past." (citation omitted)); *In re Solodyn Antitrust Litig.*, No. 14-2503, 2016 WL 6897809, at *2 (D. Mass. Sept. 19, 2016); *In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672, 690 (S.D. Fla. 2004) ("Further, to the extent that any third-party payer did charge its insureds a higher premium because of a drug company's monopolistic activities, the charging of a higher premium in the future cannot be accurately described as a 'pass on' of those charges."); *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 96-97 (D. Mass. 2007).

[31] *See, e.g.*, *In re Terazosin*, 220 F.R.D. at 680 (no evidence TPPs take cost of individual drugs into account in setting premiums); Tr. of Mot. Hr'g, *In re Aggrenox Antitrust Litig.* (D. Conn. Oct. 14, 2016), ECF No. 568 at 81-86 (Robertson Decl. Ex. A) ("The price of Aggrenox is a piece of sand, a grain of sand on the beach in terms of setting premiums . . . . when you have hundreds of thousands of drugs, the idea that any one of them is driving the premium is nonsensical.").

determined through a process of estimating future aggregate healthcare spending over the life of the contract. As a result, predicting future expenses is not a pass-on of charges previously incurred.

*Fourth*, Defendants are barred by law from asserting an End Payor pass-on defense. The Supreme Court's *Hanover Shoe* decision precludes, under federal antitrust law, arguments by defendants that overcharges have been "passed-on."[32] Several states have expressly adopted *Hanover Shoe*'s holding,[33] while others have limited any "pass-through" defense to the chain of distribution[34]—rendering a defense based on premiums and contributions wholly irrelevant here (since End-Payors do not resell products).

For these reasons, multiple courts, including courts in this Circuit, have rejected attempts to assert a premium-based pass-on defense against end-payors seeking to recover for prescription drug overcharges. In *Asacol*, for instance, the court agreed with the end-payors that "premiums do not—*as a legal or factual matter*—bear on [End Payor] damages or antitrust impact . . . ."[35] Citing a similar ruling in *Solodyn*, the court explained that, as a matter of law, it found "persuasive the reasoning of those courts that have found that insurance premiums are not a 'pass on' of alleged overcharges because premiums are set by anticipating future projected costs, not to recover money that insurers paid in the past."[36] Additionally, the court noted that, practically speaking, there was

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[32] *Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481, 487-93 (1968).

[33] *E.g.*, *Clayworth v. Pfizer, Inc.*, 49 Cal. 4th 758, 787 (2010); *Minnesota v. Philip Morris Inc.*, 551 N.W.2d 490, 497 (Minn. 1996); *K-S Pharmacies, Inc. v. Abbott Labs.*, No. 94-cv-002384, 1996 WL 33323859, at *12 (Wis. Cir. Ct. May 17, 1996); *Hyde v. Abbott Labs., Inc.*, 123 N.C. App. 572, 579 (N.C. Ct. App. 1996).

[34] Haw. Rev. Stat. § 480-13; N.M. Stat. Ann. § 57-1-3; N.Y. Gen. Bus. Law § 340(6); Neb. Rev. Stat. § 59-821.01; N.D. Cent. Code § 51-08.1-08; D.C. Code § 28-4509(b); *Bunker's Glass Co. v. Pilkington, PLC*, 206 Ariz. 9, 18 (2003) (dictum suggesting the allowance of a pass-through defense to avoid duplicative damages awards from competing groups of plaintiffs within the chain of distribution).

[35] *In re Asacol*, 2017 WL 53695, at *4 (emphasis added).

[36] *Id.* (quoting *In re Solodyn*, 2016 WL 6897809, at *2, and citing *In re Terazosin*, 220 F.R.D. at 690); *see also In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, No. 18-md-2819, 2018 WL 5094090, at *3 (E.D.N.Y. Oct. 18, 2018) (adopting the reasoning in *Asacol* and prior similar decisions).

also "no evidence that the defendants would be able to ascertain how the pricing of [a single drug product] affected premiums or the financial status of the End Payors, since End Payors reimburse prescriptions for thousands—if not tens of thousands—of different drugs and dosages."[37]

Likewise, the court in *In re Average Wholesale Price Litigation* rejected the defendants' argument that end payors passed on the cost of prescription drugs—including the alleged overcharges—to members through premiums.[38] The court observed the two-year gap between when end payors incur costs for prescription drugs and when those incurred costs might be considered in making future projections to determine premiums.[39] The court then noted the defendants' failure to show that the purpose of the end payors' premiums, in particular a portion of the premium allocated as a contribution to reserves, was to recover for previous spending on prescription drugs:

> First, there is as much as a two year lag period between the time when [Blue Cross Blue Shield of Massachusetts] incurs a cost and the time when those costs may be incorporated into the rate setting process used to determine premiums . . . [I]nsurance is a risky business and the [portion of the premium intended to be a] contribution to reserves is used to cover unforeseen risks. Defendants have failed to prove that the purpose or effect of the contribution to reserves is to recover money paid out for current claims.[40]

In sum, Purchasers respectfully seek an order barring Defendants from offering evidence or argument that their overcharges related to sales of Loestrin 24 or Minastrin 24 were somehow "passed on" in the form of higher insurance premiums or contributions by End Payors.

### F. Motion No. 6: Purchasers' Motion *in Limine* to Permit Use of the Term "Purchasers" to Refer to TPP Class Members

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[37] *Id.*

[38] *In re Pharm. Indus.*, 491 F. Supp. 2d at 96-97.

[39] *Id.*

[40] *Id.*

On occasion, Plaintiffs from all groups have used the term "purchasers" to collectively refer to themselves under one term. Defendants recently have taken issue with this usage, apparently based on the misguided belief that third-party payor ("TPP") class members (otherwise referred to as "End-Payor Plaintiffs" or "EPPs") do not fit the definition. This attempt to distinguish TPPs as something other than "purchasers" is meritless.

As the court recently explained, the named TPPs consist of "health and welfare benefit plans, health and welfare benefit funds, and employee benefit welfare funds . . . ."[41] As alleged, each TPP named plaintiff "purchases, pays and/or provides reimbursement to its employees [members, or covered lives] for some or all of the purchase price of prescription drugs" and each "indirectly purchased, paid or provided reimbursement for Loestrin 24 and/or Minastrin 24 . . . ."[42] The TPPs further allege that they "paid more for Loestrin 24 and/or Minastrin 24" than they should have and that absent Defendants' conduct they each "would have purchased less expensive generic alternatives" instead of the brand.[43] In certifying the TPP Class, the Court approved the class definition as including entities that "purchased, paid and or provided reimbursement for some or all of the purchase price for Loestrin 24 Fe and/or its AB-rated generic equivalents in any form, and/or Minastrin 24 Fe and/or its AB-rated generic equivalents . . . ."[44]

Simply put, the heart of this case involves TPPs' actual purchases or reimbursements provided to members for their actual purchases. Whether TPPs actually purchased Loestrin 24 or Minastrin or provided reimbursement for those purchases, they are still properly considered

[41] Mem, of Decision on Class Certification & Order Regarding Mots. to Exclude Certain Expert Ops. & Defs.' Renewed Mot. to Dismiss, Oct. 23, 2019, ECF No. 1274 ("EPP Class Cert. Op.") at 3.

[42] End-Payor Pls.' Second Am. Consolidated Class Action Compl., May 9, 2016, ECF No. 165 ¶¶ 15-23.

[43] *Id.*

[44] Order, Sept. 17, 2019, ECF No. 1226 ("EPP Class Cert. Order") at 2.

"purchasers." Courts, including this one, have had no problem consistently referring to TPPs as purchasers.[45] Indeed, the approved class definition states that TPP "entities 'purchased' Loestrin 24 Fe, Minastrin 24 Fe, or their generic equivalents if they indirectly purchased, paid and/or reimbursed for some or all of the purchase price."[46]

Beyond mere allegation, this Court recognized that "TPPs have the capability to retrieve information about the drugs they have purchased, the date on which they were purchased, and the price paid for the drugs."[47] Even for those entities that did not purchase generic Loestrin 24 and/or Minastrin 24, the Court held that they too were injured by virtue of their brand purchases in light of evidence that "they would have made at least a single purchase of an AB-rated generic equivalent in the but-for world."[48]

Remarkably, Defendants themselves have referred to all members of the End Payor Class, including TPPs, as "purchasers" since the early stages of the case. Because TPPs do not directly purchase product from Warner Chilcott, the alleged antitrust violator, Defendants have used the term "indirect purchasers" to describe the TPP Class, perhaps in defiance of End Payors insisting that a more appropriate appellation is "End-Payor Plaintiffs"[49] In any event, Defendants usage concedes that TPPs are nonetheless "purchasers," regardless of whether they directly or indirectly purchased product from Warner Chilcott.

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[45] *See, e.g.*, EPP Class Cert Op. at 9 (citing cases referring to TPPs as purchasers); *In re Asacol Antitrust Litig.*, 907 F.3d 42, 46 (1st Cir. 2018) ("The named plaintiffs [who consist of TPPs] and the putative class members purchased Warner's products . . . .").

[46] EPP Class Cert. Order at 2.

[47] EPP Class Cert Op. at 82.

[48] *Id.* at 87.

[49] End-Payor Pls.' Mem. of Law in Opp. to Defs.' Mot. to Dismiss the Indirect Purchaser Pls.' Consol. Class Action Compl., Mar. 24, 2014, ECF No. 92-1 at 2 n.3.

Defendants have no legitimate basis to preclude End-Payors from describing themselves as "purchasers." TPPs expressly alleged they are purchasers. Their purchases, whether directly, indirectly, or through reimbursement, are the very subject of this litigation. Courts, including this Court, have consistently referred to TPPs as "purchasers" without issue. The Court has held TPPs have evidence to prove they have made purchases to show antitrust injury. And Defendants themselves have described TPPs as purchasers, in resistance to TPPs (and consumers) referring to themselves as End-Payor Plaintiffs. The only reasonable inference that Defendants are raising this objection now is that they fear the term may sound sympathetic to a jury. But that is not enough to prevent End Payors from calling themselves what they indisputably have been defined as in this case. To prevent this issue from inconveniently resurfacing at a later date, the Court should order that Purchasers, including TPPs, are permitted to call themselves "purchasers" during trial.

### G. Motion No. 7: Purchasers' Motion to Preclude Defendants from Eliciting Testimony Regarding the Purpose For Which Any Consumer Purchased the Drugs At-Issue

Purchasers move *in limine* for an order precluding Defendants from eliciting testimony or presenting evidence regarding the purpose for which any consumer purchased the drugs at issue. Defendants have previously attempted to argue that two of the named plaintiffs are atypical, because they purchased Loestrin 24 for reasons other than to prevent pregnancy. These women purchased the medication and were charged supracompetitive prices for it. Evidence regarding the purpose for which they purchased the drugs at issue is not relevant to the jury's determinations of liability or damages, and its admission will unfairly prejudice Purchasers. Therefore, evidence of the purpose for which any consumer purchased Loestrin 24 should be excluded at trial.

The purpose for which any consumer purchased Loestrin 24 is not relevant to allegations of anticompetitive conduct or questions of antitrust injury. According to Federal Rule of Evidence

401, evidence is relevant if it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." It follows that any fact that does not make it more or less probable that Defendants engaged in anticompetitive conduct or that Purchasers sustained injury from Defendants' alleged anticompetitive conduct is irrelevant and should be excluded. "Evidence which is not relevant is not admissible."[50] Here testimony or other evidence relating to the purpose for which any consumer purchased Loestrin 24 does not make it more or less probable that Defendants violated the antitrust laws or that Purchasers were injured as a result. Accordingly, the Court should exclude any reference to the purpose for which any consumer purchased Loestrin 24 based on relevance grounds.

Courts in this Circuit have excluded evidence relating to plaintiffs' medical histories in antitrust cases. The defendants in *In re Prograf Antitrust Litigation* sought discovery regarding the plaintiffs' medical histories, including documents concerning the reason the patient was prescribed a certain formulation of the medication, arguing that the information was relevant both to the liability and damages analyses. The *Prograf* court disagreed, finding that "unlike in a medical malpractice or personal injury suit, it is difficult to see how the circumstances of this antitrust case give rise to the conclusion that consumer plaintiffs have placed their medical conditions at issue beyond their tacrolimus prescription drug history . . . . Absent good reason to overcome consumer plaintiffs' statutory privileges, [the] motion must be denied."[51]

Evidence related to the purpose for which any consumer purchased Loestrin 24 is further inadmissible because the (nonexistent) probative value of that evidence is "substantially

[50] Fed. R. Evid. 402.

[51] *In re Prograf Antitrust Litig.*, No. 11-md-02242, 2013 WL 500881, at *2 (D. Mass. Feb. 12, 2013).

outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury . . . ."[52] The only purposes for which Defendants might offer such evidence would be to embarrass Purchasers by revealing personal medical information and to distract the jury. This is entirely irrelevant to the damages and liability issues before the jury.

Accordingly, the Court should enter an order precluding Defendants from eliciting testimony or presenting evidence related to the purpose for which any consumer purchased Loestrin 24.

### H. Motion No. 8: Purchasers' Motion *in Limine* to Exclude Any Evidence or Argument Disparaging Generic Drugs or Touting the Quality or Benefits of Brand Drugs

Purchasers seek an order *in limine* to preclude Defendants from introducing evidence or argument (i) denigrating generic drugs, including with pejoratives such as "copycat" or "me too" drugs or, conversely, (ii) touting the quality or benefits of brand versions of drugs, including with self-serving descriptors such as "innovator." Such evidence and characterizations are irrelevant and inflammatory, and should be precluded.

Generic drugs are, by design and regulation, functionally identical to their brand name counterparts. As the FDA states, "A generic medicine is the same as a brand-name medicine in dosage, safety, effectiveness, strength, stability, and quality, as well as in the way it is taken and should be used . . . . The FDA Generic Drugs Program conducts a rigorous review to make sure generic medicines meet these requirements."[53] In fact, under FDA regulations, it is impermissibly "misleading" to suggest in communications to consumers a therapeutic difference between brand

[52] Fed. R. Evid. 403.

[53] FDA, *Generic Drug Facts*, (last visited Oct. 22, 2019), https://www fda.gov/drugs/generic-drugs/generic-drug-facts.

and generic drugs.[54] Thus, permitting Defendants to disparage generic drugs would be plainly counterfactual, and would misinform and mislead the jury.

Furthermore, allowing Defendants to create a specious distinction between the supposed quality of brand and generic drugs would undermine the Hatch-Waxman Act and the associated state drug substitution laws, which together represent that governments' balancing of two competing goals: (i) providing brand companies with the economic incentive to develop new drugs; and (ii) efficiently getting less expensive generic drugs to market.[55] A key element of this balance is that, after the expiration of brands' exclusivities, it is beneficial to consumers to "get generic drugs into the hands of patients at reasonable prices—fast."[56] Defendants should be precluded from mounting any rhetorical attacks on the value or role of the products necessary to effectuate this goal.

For these reasons, Purchasers seek an order preventing Defendants from introducing evidence or argument denigrating generic drugs or touting the quality or benefits of brand drugs.

## I. Motion No. 9: Purchasers' Motion *in Limine* to Require Defendants to Produce Witnesses for Purchasers' Case-in-Chief That They Themselves Will Bring to Trial

As a matter of fairness, Purchasers should have the option to call Defendants' witnesses live during Purchasers' case-in-chief rather than relying on deposition testimony. The key factual testimony in support of Purchasers' claims will likely come from Defendants' former employees.

[54] *See, e.g.*, *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 615 (2011) (requiring warnings with a generic but not the branded version of a drug "would inaccurately imply a therapeutic difference between the brand and generic drugs"); *Schering Corp. v. FDA*, 51 F.3d 390, 396 (3d Cir. 1995) (FDA regulatory requirements act "as a market entry restriction imposed to ensure that generic drugs will be as safe and effective as their pioneer drug counterparts"); *Meijer, Inc. v. Warner Chilcott Holdings Co. III, Ltd.*, 246 F.R.D. 293, 297 (D.D.C. 2007) ("FDA-approved generic drugs are . . . completely interchangeable with that branded drug.").

[55] *See, e.g.*, *Abbott Labs. v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990).

[56] *In re Barr Labs, Inc*., 930 F.2d 72, 76 (D.C. Cir. 1991).

Because these individuals are former employees who are geographically dispersed, few, if any, of these witnesses can be compelled by Purchasers to appear at trial under the Court's subpoena power. Juries pay better attention to live witnesses and are notoriously bored by spliced video clips. Relegating Purchasers' presentation of evidence to assorted video depositions while Defendants offer live testimony compromises the fundamental fairness of the trial.

Purchasers seek this order after several attempts to resolve the issue with Defendants. By mid-October, discussions had ceased as Defendants were unable to confirm the availability of the witnesses. Therefore, on October 15, Purchasers submitted a letter to the Court seeking guidance concerning the appearance of witnesses live in the Purchasers' case-in-chief. Since then, discussions have resumed. To the extent those discussions are not fruitful, Purchasers seek an order requiring Defendants to make available for Purchasers' case-in-chief, those live witnesses that Defendants themselves intend to bring to trial.

The Court has substantial jurisdiction over the presentation of evidence at trial under Federal Rule of Evidence 611(a), and courts have repeatedly precluded defendants from calling their own witnesses to testify live at trial after failing to produce those witnesses for the opposing parties' case-in-chief.[57]

[57] *See, e.g.*, *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, No. 05-12237, 2007 WL 6335374, at *1 (D. Mass. Aug. 10, 2007) (pre-trial memorandum of defendant noting that the court "stated that an adverse party can call as a live witness in its case any witness identified to be called live by the other party"), ECF No. 807; *Buchwald v. Renco Grp., Inc.*, No. 13-cv-7948, 2014 WL 4207113, at *1 (S.D.N.Y. Aug. 22, 2014) ("To prevent unfairness and avoid wasting time, numerous courts have held that a party may not limit a witness that the party intends to call at trial from testifying only during its own case in chief.") (collecting cases); *In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 11-cv-00195, 2013 U.S. Dist. LEXIS 94121, at *6-7 (S.D.W. Va. July 5, 2013) (holding that it would be inequitable to permit a party to call a witness to testify live during its case-in-chief and then make the same witness unavailable to testify live for the opposing party); *Eolas Techs., Inc. v. Microsoft Corp.*, 270 F. Supp. 2d 997, 1001 (N.D. Ill. 2003); *Niebur v. Cicero*, 212 F. Supp. 2d 790, 806-807 (N.D. Ill. 2002).

In *R.B. Matthews, Inc. v. Transamerica Transportation Services, Inc.*, for example, the Ninth Circuit condemned the defendant's "gamesmanship" in refusing to produce live witnesses for the plaintiffs' case-in-chief and affirmed the trial court's exclusion of live testimony during the defendant's case.[58] The court reasoned that if the defendant "had truly wished to present the live testimony of [its employees], it could have done so by making those witnesses available when [the plaintiff] requested that they be produced."[59] Similarly, in *Eolas Technologies, Inc. v. Microsoft Corp.*, the court granted a motion *in limine* requiring the defendant to make employees that it intended to call as defense witnesses available to testify during the plaintiff's case-in-chief.[60]

As these decisions recognize, a witness is either available to testify at trial or not. To allow Defendants to present live witnesses to the jury while consigning Purchasers to spliced video clips would unfairly disadvantage Purchasers' ability to try their case. Requiring live testimony also better serves the jury. "[I]t is well recognized that live testimony is preferred over videotaped depositions or other means of presenting evidence."[61] Live testimony better facilitates the jury's efforts to ascertain the truth, in part because jurors pay more attention to live witnesses. As the court observed in *In re Actos (Pioglitazone) Products. Liability Litigation*:

> [C]ontemporaneous transmission of live witness testimony will better allow the jury to more realistically see the live witness along with his hesitation, his doubts, his variations of language, his confidence or precipitancy, his calmness or consideration, without editing or the unavoidable esthetic distance created by a video deposition and, thus, more fully and better satisfy the goals of live, in-person testimony . . . .[62]

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[58] 945 F.2d 269, 273 (9th Cir. 1991).

[59] *Id.*

[60] 270 F. Supp. 2d at 1001.

[61] *InfoMC, Inc. v. Comprehensive Behavioral Care, Inc.*, No. 10-cv-4907, 2012 WL 1114360, at *17 (E.D. Pa. Mar. 30, 2012).

[62] *In re Actos (Pioglitazone) Prods. Liab. Litig*., No. 12-cv-00064, 2014 WL 107153, at *8 (W.D. La. Jan. 8, 2014) (internal quotation marks omitted).

And, in *Traylor v. Husqvarna Motor*, the Seventh Circuit granted the plaintiffs a trial in which an expert's direct examination was conducted live, but the cross-examination was presented to the jury via video-tape.[63] Judge Posner, writing for the court, explained that such "'dual media' testimony is generally . . . a bad idea" because, as "common sense" dictates, "a living person generally conveys a stronger impression than does his [taped testimony]."[64]

Although Purchasers will have an opportunity to cross-examine Defendants' live witnesses, Purchasers are at a distinct disadvantage if forced to present their case-in-chief through snippets of video while Defendants present their case through live witnesses.[65] This scenario would raise the same problems identified by Judge Posner, namely, that the live testimony offered on behalf of Defendants will have "artificially greater salience" than the recorded testimony shown by Purchasers.[66] To make the trial "effective for determining the truth,"[67] this sort of "thumb on the scale" should be prevented: Defendants' witnesses should be made available live for both parties or for neither.

This Court should use its inherent authority over the conduct of the trial to ensure a balanced and efficient presentation of the evidence by requiring that Defendants make the witnesses it intends to call live in its case-in-chief also available in the same manner to the Purchasers. If a witness for Defendants is available to testify at trial, then Defendants should make that witness available to Purchasers for their case-in-chief.[68]

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[63] 988 F.2d 729, 734 (7th Cir. 1993).

[64] *Id.*

[65] Purchasers would retain the right to proceed with the witness via live examination or deposition designations.

[66] *Traylor*, 988 F.2d at 734.

[67] Fed. R. Evid. 611(a)(1).

[68] Purchasers would retain the right to proceed with the witness via live examination or deposition designations.

Accordingly, Purchasers request that the Court grant this motion and allow Purchasers the option to call Defendants' witnesses live during Purchasers' case-in-chief rather than relying on deposition testimony.

### J. Motion No. 10: Purchasers' Motion *in Limine* to Preclude Defendants From Playing Deposition Clips During Purchasers' Case-in-Chief, Unless Testimony is Cross-Examination or Necessary for Completeness

Purchasers respectfully request an order from this Court precluding Defendants from playing deposition testimony in the Purchasers' case-in-chief, except when such testimony represents proper cross-examination of the testimony played in Purchasers' case-in-chief or is necessary for completeness.

Rule 32 of the Federal Rules of Civil Procedure addresses the use of deposition testimony at trial and provides: "If a party offers in evidence only part of a deposition, an adverse party may require the offeror to introduce other parts that in fairness should be considered with the part introduced, and any party may itself introduce any other parts."[69]

As the cited language indicates, Defendants should be permitted to play clips from the same deposition only as required by "fairness." In other words, cross-examination on the topics raised in Purchasers' direct examination may be played during Purchasers' case-in-chief, and any additional clips that are required for completeness may be played.[70] To the extent that Defendants wish to play portions of deposition testimony that are neither related to cross-examination nor necessary for completeness, those clips may be played during Defendants' case-in-chief.

[69] Fed. R. Civ. P. 32(a)(6).

[70] *See* Fed. R. Evid. 106; *Smith v. Schwan's Home Serv., Inc*., No. 13-cv-00231, 2014 WL 6679129, at *5 n.10 (D. Me. Nov. 25, 2014).

This Court should reject any efforts by Defendants to play portions of depositions during the Purchasers' case-in-chief for reasons other than those set forth above. Consistent with the advisory committee notes to Rule 32, "the rules of evidence are to be applied to depositions offered at trial as though the deponent were then present and testifying at trial."[71] Under Federal Rule of Evidence 611, the scope of cross-examination "should not go beyond the subject matter of the direct examination and matters affecting the witness's credibility."[72] Although Rule 611 also states that the Court "may allow inquiry into additional matters as if on direct examination,"[73] the advisory committee notes state that the rule was changed, in most situations, to limit questioning to the scope of direct examination. The notes observe that "the factors of insuring an orderly and predictable development of the evidence weigh in favor of the narrower rule, especially when discretion is given to the trial judge to permit inquiry into additional matters."[74] Thus, in treating depositions as the Court would treat a live witness, the Court should rarely use its discretion to allow further questioning outside the scope of direct examination. This is particularly true in light of Rule 32(a)(6)'s provision that "any party may itself introduce any other parts [of the deposition]"[75]—language which indicates that Defendants would have to "introduce" other parts of the deposition themselves—*i.e.*, in their case-in-chief. Hence, testimony by Defendants in Purchasers' case-in-chief should be limited to cross-examination of the subject matter.

First Circuit case law is also in accord with this procedure. For instance, in *Nickerson v. G.D. Searle & Co.*, the First Circuit held that the trial court acted appropriately on each of the three

[71] Fed. R. Civ. P. 32 advisory committee's notes to 1970 amendment.

[72] Fed. R. Evid. 611(b).

[73] *Id.*

[74] Fed. R. Evid. 611(b) advisory committee's notes to 1974 amendment.

[75] Fed. R. Civ. P. 32(a)(6).

occasions that it declined to allow additional portions of an expert's deposition to be read on cross-examination because the court's rulings were based on a careful examination of the deposition.[76] Such a case-by-case review for fairness—when the parties cannot agree themselves—is precisely what the Purchasers are seeking here. Defendants should not be permitted to essentially commandeer the Purchasers' case-in-chief by playing long stretches of testimony on issues not raised by the Purchasers in their case-in-chief.

For the foregoing reasons, Purchasers respectfully request that the Court prevent Defendants from including in their counter-designations any testimony that is not proper cross-examination—*i.e.*, within the scope of direct or addressed to credibility—unless the designated testimony is necessary to complete an answer. Any examination on new subjects may take place during Defendants' case-in-chief.

### K. Motion No. 11: Purchasers' Motion *in Limine* to Preclude Argument or Evidence Related to Defendants' Supposed Good Character or Reputation

Defendants may attempt at trial to introduce supposed good character or reputation evidence, *e.g.*, evidence of good corporate citizenship, internal corporate governance controls, socially valuable research and development efforts, efforts to increase access to pharmaceuticals or other healthcare, or charitable works. All such evidence, however, would be irrelevant and inadmissible character evidence in violation of Federal Rules of Evidence 401, 402 and 404. Accordingly, the Court should prohibit Defendants from introducing evidence of the defendant companies' character or reputation at trial.

Evidence regarding Defendants' supposed character or reputation as good corporate citizens, internal corporate governance controls, and other similar evidence is not relevant to any

[76] 900 F.2d 412, 419 (1st Cir. 1990).

issue in this case. In *Bartlett v. Mutual Phamaceutical Co., Inc.*, for example, the court granted a motion *in limine* to exclude any references "to any good acts done by Mutual Pharmaceuticals (such as charitable donations or discounted drugs for the needy)" because "such 'unrelated good acts' evidence. . . is *not relevant, see Fed. R. Evid. 401, 402.*"[77]

The sole purpose, and probable effect, of introducing evidence relating to any of Defendants' internal corporate governance controls, supposed good character, or charitable works would be to persuade the jury that Defendants were less likely to have participated in the anticompetitive scheme alleged by Purchasers because of their supposed good character or reputation. Such character evidence is inadmissible and should be excluded, including under Federal Rule of Evidence 404(a), which provides that "[e]vidence of a person's character or character trait is not admissible to prove that on a particular occasion the person acted in accordance with a character trait." As noted by the Advisory Committee on the Federal Rules of Evidence:

> After careful consideration over a number of years, the Evidence Rules Committee has concluded that character evidence should not be admitted to prove conduct in a civil case. The circumstantial use of character evidence is fraught with peril in any case, because it could lead to a trial of personality and could cause the jury to decide the case on improper grounds.[78]

In addition to excluding such evidence under Federal Rules of Evidence 401 and 402, *Bartlett*[79] also held evidence of Mutual Pharmaceuticals' charitable donations and discounts to be

[77] *Bartlett v. Mut. Pharm. Co., Inc.*, No. 08-cv-358, 2010 WL 3156555, at *4 (D.N.H. July 26, 2010) (emphasis added); *see also Niver v. Travelers Indem. Co. of Ill.*, 433 F. Supp. 2d 968, 994-95 (N.D. Iowa 2006) (excluding charitable acts of insurance company in coverage action on basis of relevance).

[78] Report of the Advisory Comm. on Evidence Rules, Administrative Office of the U.S. Courts FRE Amendments to Rules 404, 408, 606, and 609 (May 16, 2005).

[79] *Bartlett*, 2010 WL 3156555, at *4.

"*impermissible character evidence, see Fed. R. Evid. 404(a)*, 608."[80] Introduction of good character evidence would also necessitate permitting Purchasers to introduce evidence regarding Defendants' bad deeds to balance Defendants' evidence. Exclusion of all such character evidence would preclude needing to hold an almost mini-trial to assess the weight of the good and bad character evidence.

For the foregoing reasons, Purchasers respectfully request that this Court prohibit Defendants from introducing evidence related to the defendant companies' good character or reputation.

### L. Motion No. 12: Purchasers' Motion *in Limine* to Exclude Any Reference to the Adverse Impact That a Damages Award Would Have on Defendants or the Drug Industry

Purchasers seek an order *in limine* to preclude Defendants from arguing that a large judgment would (1) negatively impact their current businesses, including, but not limited to, putting it out of business or causing job losses, reduced spending on new drug research, or losses to investors; (2) adversely affect the pharmaceutical industry in general; or (3) require price increases for brand or generic Loestrin 24, Minastrin 24, or other products.

[80] *Id.* (emphasis added); *see also Fecho v. Eli Lilly & Co.*, 914 F. Supp. 2d 130, 137-38 (D. Mass. 2012) (evidence of a physician's character not admissible to establish the physician's conduct in prescribing medication on a particular occasion); *Dunn v. State Farm Mut. Auto. Ins. Co.*, 264 F.R.D. 266, 275-76 (E.D. Mich. 2009) (prior jury finding that intervenor-plaintiff Healthcall of Detroit, Inc., a health care provider, fraudulently billed defendant insurance company on an earlier occasion was inadmissible under Fed. R. Evid. 404, where the defendant sought to use the evidence to establish that Healthcall had "a propensity for fraudulent conduct"); *Becker v. ARCO Chem. Co.*, 207 F.3d 176, 203 (3d Cir. 2000) (in an age discrimination suit, evidence of improprieties surrounding defendant's termination of a different employee three years prior "solely to establish [defendant's] propensity to fabricate reasons to justify terminating its employees so that the jury would conclude that [defendant] did the same thing when it dismissed [plaintiff] . . . is precisely the kind prohibited . . . [by Fed. R. Evid. 404]" (citation omitted)); *Unit Drilling Co. v. Enron Oil & Gas Co.*, 108 F.3d 1186, 1194 (10th Cir. 1997) (defendant corporation's breach of contract with a third party inadmissible under Fed. R. Evid. 404 "to prove that [it] typically breached contracts and, therefore, that [it] breached its contract with [the plaintiff]" (citation omitted)).

The financial impact of an adverse verdict on Purchasers, the pharmaceutical industry, or drug prices is not relevant to any issue in this case and, permitting such arguments, would be unduly prejudicial. The issues before the jury concern Defendants' anticompetitive conduct and its consequences on Purchasers. Moreover, the purpose of compensatory damages is to make plaintiffs whole.[81] In antitrust cases, plaintiffs are made whole by an award of the amount of overcharges resulting from the defendants' antitrust violations.[82] A defendant's financial standing, ability to pay damages, or reaction to a damages award is beyond the scope of that inquiry and could be unduly prejudicial.[83]

Courts have made clear that it is inappropriate for a defendant to introduce evidence about the effects of a potential verdict on a defendant's business or on the price of products because such evidence could be unduly prejudicial. In *Long v. TRW Vehicle Safety Systems*, for instance, the plaintiffs moved to preclude suggestions that a damage award would "drive up the price of products, put the manufacturers out of business, or cause job losses."[84] The court agreed that "any such suggestions would be irrelevant and inadmissible" and granted the motion.[85] And, in *Rebolledo v. Herr-Voss Corp.*, the court granted a motion *in limine* to exclude argument by the

[81] *King v. McMillan*, 594 F.3d 301, 314 (4th Cir. 2010); *Ill. Sch. Dist. Agency v. Pac. Ins. Co. Ltd.*, 571 F.3d 611, 617 (7th Cir. 2009); *Calhoun v. Yamaha Motor Corp., U.S.A.*, 216 F.3d 338, 347 (3d Cir. 2000) (citing *Saldana Sanchez v. Vega Sosa*, 175 F.3d 35, 36 (1st Cir. 1999)).

[82] *In re Nexium*, 296 F.R.D. at 55.

[83] *CardiAQ Valve Techs., Inc. v. Neovasc Inc.*, No. 14-cv-12405, 2016 U.S. Dist. LEXIS 54835, at *5-7 (D. Mass. Apr. 25, 2016) ("Neovasc may not present any evidence about its ability to pay a damages award or the impact of any damages award."); *see also Draper v. Airco, Inc.*, 580 F.2d 91, 95 (3d Cir. 1978) (party's use of its financial status as a way to create sympathy from a jury is improper); *Hicks v. Ass'n of Apartment Owners of Makaha Valley Plantation*, No. 14-00254, 2016 U.S. Dist. LEXIS 87956, at *2 (D. Haw. July 7, 2016).

[84] No. 09-2209, 2011 U.S. Dist. LEXIS 119111, at *31 (D. Ariz. Oct. 14, 2011).

[85] *Id.*

defendant that an adverse judgment would cause it financial harm.[86] The court explained that such argument and evidence is "not relevant and would only appeal to the sympathy of the jury."[87]

Accordingly, Purchasers seek an order precluding Defendants from arguing that a large judgment would negatively impact their current businesses, adversely affect the pharmaceutical industry, or require drug price increases.

### M. Motion No. 13: Purchasers' Motion *in Limine* to Preclude Evidence That the Sales of Loestrin (a) Generated Profits That Were Used to Develop New Products or Otherwise Benefit Defendants or the Public, or (b) Allowed Warner Chilcott to Recoup Research and Development Costs

Purchasers move to preclude Defendants from offering evidence or argument that the suppression of full-fledged generic Loestrin entry was beneficial or procompetitive because it: (a) generated profits used to develop new products or otherwise benefitted the defendant companies or the public; or (b) purportedly allowed Warner Chilcott to recoup research and development ("R&D") costs incurred in developing Loestrin. Neither assertion is relevant to any claim or defense in this case, and therefore would only confuse and mislead the jury. Accordingly, Defendants should be prohibited from offering such evidence or making such arguments under Federal Rules of Evidence 401, 402, and 403.[88]

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[86] 101 F. Supp. 2d 1034, 1036-37 (N.D. Ill. 2000).

[87] *Id.* at 1036 (invoking Fed. R. Evid. 403); *see also Stoner v. Wal-Mart Stores, Inc.*, No. 06-4053, 2009 U.S. Dist. LEXIS 130969, at *2 (C.D. Ill. Aug. 18, 2009) (barring argument or evidence that "a judgment in [plaintiff's] favor would create a hardship for defendants or anyone else"); *Walker v. Casey's Gen. Stores, Inc.*, No. 07-3229, 2009 U.S. Dist. LEXIS 114868, at *9 (C.D. Ill. Dec. 9, 2009) (excluding any argument that damage award would be passed on to the general public or that it would cause hardship to defendant).

[88] Pursuant to Rule 402, "[i]rrelevant evidence is not admissible." Fed. R. Evid. 402. Evidence is not relevant unless "it has a tendency to make a fact more or less probable than it would be without the evidence," and "the fact is of consequence in determining the action." Fed. R. Evid. 401. Moreover, even relevant evidence may be excluded "if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403.

Whether Warner Chilcott's ability to charge supracompetitive prices generated profits used to develop new products or to otherwise benefit Warner Chilcott or the public is irrelevant to this case because "the Sherman Act presumes that competition, not cartel pricing, best ensures quality products for consumers . . . ."[89] Supracompetitive prices are not justifiable "as a mere *quid pro quo* for providing consumers with better products."[90] The court in *United States v. United Shoe Machinery Corp.* thus rejected a monopolist's excuse that "only through the existence of some monopoly power" could the industry "support fundamental research."[91] The court reasoned:

> To this defense the shortest answer is that the law does not allow an enterprise that maintains control of a market through practices not economically inevitable, to justify that control because of its supposed social advantage. It is for Congress, not for private interests, to determine whether a monopoly, not compelled by circumstances, is advantageous. And it is for Congress to decide on what conditions, and subject to what regulations, such a monopoly shall conduct its business.[92]

While patents reward and incentivize brand companies by granting them a monopoly,[93] that reward goes only so far as the patent is valid, infringed, enforceable, and not expired.[94] A patent holder may not justify a payment to extend the life or exclusionary effect of its patent, beyond that to which it is entitled under the law, by arguing that such extended exclusivity and

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[89] *Freeman v. San Diego Ass'n of Realtors*, 322 F.3d 1133, 1152 (9th Cir. 2003); *see also* Phillip E. Areeda & Herbert E. Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application, VII* ¶1504c, at 419 (4th ed. 2017) (courts "are not to inquire whether the restraint promotes the 'public interest' but only whether it increases competition").

[90] *Freeman*, 322 F.3d at 1152 (emphasis added).

[91] 110 F. Supp. 295, 345 (D. Mass. 1953).

[92] *Id.* (citation omitted); *see also Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 37-38 (D.C. Cir. 2005) (rejecting, as a procompetitive defense, the argument that, absent the challenged restraint, a joint venture "would be less likely to create future products," and reasoning that "[a] restraint cannot be justified solely on the ground that it increases the profitability of the enterprise that introduces the new product").

[93] *See, e.g., In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 666 (D. Conn. 2016) ("Patents, of course, allow [brand manufacturers] to [charge supracompetitive prices] lawfully, so long as the drug in question remains under patent protection.").

[94] *See FTC v. Actavis, Inc.*, 570 U.S. 136, 147 (2013).

associated increased sales of the brand product (here Loestrin) are necessary to incentivize the brand company to further innovate or develop other pharmaceutical products that purportedly benefit the public. As a matter of law, the incentive to innovate is whatever exclusivity the patent confers while it is viable, and no more.[95] Consequently, evidence related to the use of profits generated by an allegedly anticompetitive scheme is inadmissible and must be excluded.

Furthermore, Defendants' "beneficial use of monopoly profits" justification is not permitted because it is essentially an argument that full-fledged generic competition would prevent Warner Chilcott from obtaining monopoly profits to reinvest in allegedly socially beneficial ways. Permitting Defendants to justify their conduct with an appeal to the public good would necessarily imply that full-fledged generic competition is itself unreasonable. Such a defense is not cognizable under textbook antitrust law.[96]

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[95] *See id.* ("[A valid patent] may permit the patent owner to charge a higher-than-competitive price for the patented product. But an *invalidated* patent carries with it no such right."); *see also, e.g.*, *In re Aggrenox*, 199 F. Supp. 3d at 666 (noting that while patents allow innovators to charge monopoly prices for a time, Congress has also "made the policy decision to create incentives for generic manufacturers to challenge drug patents they perceive to be vulnerable, thereby encouraging competition"); *New York v. Actavis, PLC*, No. 14-cv-7473, 2014 WL 7015198, at *45 (S.D.N.Y. Dec. 11, 2014) (explaining that "incentives for innovation" stem from "truly innovative conduct," not by "[p]roviding financial rewards for anticompetitive conduct," where the defendant argued that a restraint that foreclosed generic entry was justified by prospects for innovation); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1296 (S.D. Fla. 2005) (holding that while the patent power to exclude is an "incentive to induce investment in innovation," it is also limited by "the risk that the patent later will be held invalid").

[96] *See, e.g.*, *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 117 (1984); *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 696 (1978); *Meijer, Inc. v. Barr Pharms., Inc.*, 572 F. Supp. 2d 38, 63 n.24 (D.D.C. 2008) ("Although the Court does not reach the merits of Barr's proffered procompetitive benefits, the Court notes that 'benefits' are only procompetitive when they promote and protect competition, not competitors, and when they do not rely on the assumption that competition itself is unreasonable." (citations omitted)); *LePage's Inc. v. 3M*, 324 F.3d 141, 163-64 (3d Cir. 2003) (defense that defendant was merely "act[ing] in furtherance of its economic interests does not constitute the type of business justification that is an acceptable defense to § 2 monopolization").

It is also well established that generic drug competition is procompetitive, while suppressing generic drug competition is anticompetitive. *See, e.g.*, *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1311 n.27 (11th Cir. 2003) ("[T]he anticompetitive effects of exclusion [of generic drugs] cannot be seriously debated."); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 910-11 (6th Cir. 2003); *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1051-52 (N.D. Ill. 2003) (suppressing generic competition is anticompetitive, even though generic competition may constitute "free riding"), *overruled on other grounds*, 403 F.3d 1328 (Fed. Cir. 2005); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 423 (D. Del. 2006) (preventing generic substitution is actionable anticompetitive conduct).

Defendants should also be precluded from arguing that Warner Chilcott's supracompetitive pricing was justified because it aided Warner Chilcott in recouping their R&D costs for Loestrin or other sunk costs. This argument is not relevant to Warner Chilcott's market power. It is also prejudicial because it would mislead the jury by improperly suggesting that the reverse payment from Warner Chilcott to Watson was justified because Warner Chilcott incurred sunk costs to develop Loestrin. But "the purported need for brand manufacturers to exclude . . . competitors in order to recoup costs is . . . an argument for Congress, and outside the scope of this antitrust litigation."[97]

Accordingly, Purchasers respectfully request that this Court prohibit Defendants from introducing evidence that suppression of full-fledged generic competition to Loestrin was in any way procompetitive or beneficial because it, *inter alia*, (a) generated profits that were used to develop or discover new drugs or otherwise benefit Defendants or the public; or (b) allowed Warner Chilcott to recoup research and development costs or other sunk costs.

### N. Motion No. 14: Purchasers' Motion *in Limine* to Preclude Argument or Evidence Regarding Past or Present Litigation Involving Purchasers or Their Counsel

Purchasers move *in limine* for an order precluding Defendants from referring to or presenting evidence on any other current or past cases involving Purchasers or their counsel—including other reverse payment litigation. Involvement in other cases is not relevant to the jury's determination of Defendants' liability here, and admission of such information would serve only to unfairly prejudice Purchasers.

[97] *In re Aggrenox*, 199 F. Supp. 3d at 666.

Evidence is relevant if: "(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action."[98] The facts of consequence here center on whether Defendants engaged in anticompetitive conduct and whether Purchasers sustained injury as a result of that conduct. Whether or not Purchasers or their counsel currently are, or ever were, involved in other reverse payment litigation has no bearing on the facts at issue in this case.[99]

The only reason Defendants would conceivably reference the involvement of Purchasers or their counsel in other reverse payment litigation would be to suggest that Purchasers are "serial" plaintiffs or that the case is lawyer-driven. Neither purpose is permissible. Attempts to use evidence of other lawsuits to demonstrate a plaintiff's purported "litigious character" are improper under Federal Rule of Evidence 404.[100] And arguments and insinuations concerning the motives or character of Purchasers' lawyers have no bearing at all on the merits of this case.[101]

Moreover, evidence concerning Purchasers' or their lawyers' involvement in other litigations should be excluded because such evidence creates a significant danger of prejudice, confusion and waste of time.[102] As the First Circuit held in *Kinan v. City of Brockton*, introduction of evidence concerning other litigations will likely cause undue prejudice, "confusion and the

[98] Fed. R. Evid. 401.

[99] *See* Fed. R. Evid. 402 ("Irrelevant evidence is not admissible."); *see also In re Lidoderm Antitrust Litig.*, Mot. for Recons. re Proof to Establish Causation, Feb. 7, 2018, No. 14-02521, ECF No. 978 at 9 (barring defendants from "comment[ing] on other litigation plaintiffs have been involved with").

[100] *See Barker v. Yassine*, No. 11-cv-00246, 2016 WL 4264149, at *2 (E.D. Cal. Aug. 15, 2016).

[101] *See, e.g., In re Yasmin & Yaz (Drospirenone) Mktg.*, No. 09-md-2100, 2011 WL 6740391, at *16 (S.D. Ill. Dec. 22, 2011) (prohibiting defendant from using terms such as "lawsuit abuse" and "lawyer driven litigation").

[102] Fed. R. Evid. 403 (permitting exclusion of relevant evidence if its probative value is outweighed by danger of "unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.").

consumption of a great deal of unnecessary time," outweighing any "remote relevancy" the evidence might have.[103]

Accordingly, Purchasers request that the Court enter an order precluding Defendants, and their counsel and any witnesses, from arguing, insinuating or presenting evidence to the jury concerning other past or present litigation involving Purchasers or their counsel.

### O. Motion No. 15: Purchasers' Motion *in Limine* to Exclude References to Treble Damages, Attorney Fees and Costs

Purchasers move for an order barring Defendants from offering any evidence or argument regarding any Purchaser's ability to recover treble damages, attorneys' fees, or costs. Any such evidence is irrelevant, would improperly interfere with the jury's fact-finding role, and would unfairly prejudice Purchasers. Treble damages are mandated by the Clayton Act, 15 U.S.C. § 15, "to encourage private plaintiffs to bring suit," and "[a]ny ultimate recovery totaling less than three times proven damages would weaken the statutory incentive through judicial construction."[104] Any reference to treble damages poses a risk that the jury would award lower damages than Congress intended.[105] In other reverse payment cases, Defendants have either agreed to avoid referencing these issues or the Court has held that the defendants could not reference treble

[103] 876 F.2d 1029, 1034-35 (1st Cir. 1989); *see also CPC Int'l, Inc. v. Northbrook Excess & Surplus Ins. Co.*, 144 F.3d 35, 44 (1st Cir. 1998) (evidence of other litigations could "lead to a decision based on emotion or a desire to punish," warranting exclusion); *Martensen v. Koch*, No. 13-cv-02411, 2015 WL 332694, at *2 (D. Col. Jan. 26, 2015) (excluding evidence of other litigations because "the dangers of unnecessarily misleading the jury, confusing the issues, and unduly delaying the trial will substantially outweigh whatever marginal probative value this evidence might have . . .").

[104] *Gulfstream III Assocs., Inc.*, 995 F.2d at 448 (3d Cir. 1993) (citation omitted).

[105] *See Brooks v. Cook*, 938 F.2d 1048, 1052 (9th Cir. 1991) ("The majority rule is that it is error for a court to instruct a jury that it will subsequently treble any damages the jury awards."); *In re Cathode Ray Tube (CRT) Antitrust Litig.*, No. C-07-5944, 2016 U.S. Dist. LEXIS 166396, at *228 (N.D. Cal. Oct. 25, 2016) (informing the jury of trebling under the Clayton Act "is an invitation to the jury to negate Congress' determination that actual damages should be trebled" in order to deter antitrust violations and encourage private enforcement of the antitrust laws (quotations, citation omitted)).

damages.[106] Similarly, courts have concluded that the jury should not be aware of the plaintiffs' potential right to receive attorneys' fees and costs, as these, too, "might lead the jury to offset the fees by reducing the damage award."[107]

### A. Motion No. 16: Purchasers' Motion *in Limine* to Exclude Any Evidence Regarding the Relative Size or Financial Condition of Purchasers, Class Members and Defendants

Purchasers move *in limine* for an order precluding Defendants, their counsel, and their witnesses from offering evidence or making reference to the relative size of Purchasers (including absent class members) and Defendants, or to Purchasers' financial condition, before the jury. The relative size of the corporate entities, number of employees, or the financial resources of Purchasers' and/or absent class members as compared to those of Defendants is not relevant to allegations of anticompetitive conduct or to questions of antitrust injury. Therefore, such evidence should be excluded at trial.

According to Federal Rule of Evidence 401, evidence is relevant if it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Any fact that does not make it more or less probable that Defendants engaged in anticompetitive conduct or that Purchasers sustained injury from Defendants' alleged anticompetitive conduct is irrelevant and should be excluded. "Evidence which is not relevant is not admissible."[108] Testimony or other evidence

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[106] *In re Lidoderm Antitrust Litig.*, Mot. for Recons. re Proof to Establish Causation, Feb. 7, 2018, No. 14-02521, ECF No. 978 at 10; *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-2503-DJC, ECF No. 1089 (D. Mass. Mar. 8, 2018*); In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-2409-WGY, ECF No. 1077 (D. Mass Oct. 17, 2014).

[107] *Brooks*, 938 F.2d at 1052; *HBE Leasing Corp. v. Frank*, 22 F.3d 41, 45-46 (2d Cir. 1994) (collecting "cornucopia" of case law and stating: "In th[e] context [of antitrust violations] as well, courts have uniformly concluded that mentioning treble damages and attorneys fees to the jury is improper.").

[108] Fed. R. Evid. 402.

relating to the relative size of Purchasers and/or absent class members compared to Defendants or their financial condition does not tend to make it more or less probable that Defendants violated the Sherman Act or that Purchasers were injured as a result.

Case law supports the exclusion of evidence of evidence regarding the relative size of the parties[109] and of Purchasers' financial condition.[110] "Courts have routinely denied access to personal financial records in civil discovery . . . ."[111] These considerations are irrelevant to Purchasers' claims, namely, whether Defendants violated the Sherman Act and whether Purchasers were injured as a result.[112] Furthermore, evidence of the parties' relative size and plaintiffs' financial status should be excluded because the probative value, if any, is "substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury . . . ."[113]

## II. MOTIONS RELATED TO REVERSE PAYMENTS

### A. Motion No. 17: Purchasers' Motion *in Limine* to Exclude Arguments or Evidence That Authorized Generics are Anticompetitive

[109] *3A Composites USA, Inc. v. United Indus., Inc.*, No. 16-cv-5017, 2017 WL 5991968, at *2 (W.D. Ark., Sept. 18, 2017); *Hassebrock v. Air & Liquid Sys. Corp.*, No. 14-cv-1835, 2016 WL 4496917, at *8 (W.D. Wash. April 11, 2016) ("The Court will exclude any argument comparing the relative size and financial positions of the parties.").

[110] "The general rule is . . . no reference should be made to the wealth or poverty of a party . . . ." *Brough v. Imperial Sterling Ltd.*, 297 F.3d 1172, 1178 (11th Cir. 2002) (applying Florida law). "Evidence of a party's financial condition is generally not relevant and can be unduly prejudicial, as it can distract the jury from the real issues in the case." *In re Homestore.com, Inc. Sec. Litig.*, No. 01-cv-11115, 2011 U.S. Dist. LEXIS 10677, at *7 (C.D. Cal. Jan. 25, 2011) (evidence of named plaintiff's financial condition not admissible).

[111] *Freese v. FDIC*, 837 F. Supp. 22, 24 (D.N.H. 1993), *vacated as moot*, 70 F.3d 1252 (1st Cir. 1994).

[112] *Sanderson v. Winner*, 507 F.2d 477, 479-480 (10th Cir. 1974) ("Ordinarily courts do not inquire into the financial responsibility of litigants."). *See also Draper v. Airco, Inc.*, 580 F.2d 91, 95 (3d Cir. 1978) (improper to use party's financial status as a way to create sympathy from a jury); *Slantis v. Capozzi & Assocs., P.C.*, No. 09-cv-00049, 2010 U.S. Dist. LEXIS 79866 at *12 (M.D. Pa. Aug. 9, 2010) (evidence of plaintiff's financial obligations irrelevant).

[113] Fed. R. Evid. 403; *In re Homestore.com*, 2011 U.S. Dist. LEXIS 10677, at *7 (evidence of a party's financial condition can be "unduly prejudicial").

Purchasers respectfully request a ruling that Defendants are not permitted to introduce evidence or argument that authorized generics are anticompetitive or deter generic pharmaceutical companies from challenging patents or launching generic versions of drugs. Such evidence constitutes improper lay opinion under Rule 701 and is also highly misleading and risks juror confusion under Rule 403.

The Hatch-Waxman Act grants the first paragraph IV ANDA filer a 180-day exclusivity period to market a generic version of a prescription drug, during which time the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug.[114] However, a brand manufacturer can launch an authorized generic version of its own brand drug under its own NDA during the first-filer's 180-day exclusivity period. These authorized generic launches are legal[115] and considered procompetitive by the FDA.[116] After studying the effects of authorized generics, the FTC concluded that "authorized generics appear not to have substantially altered generic firms' willingness to enter by challenging questionable patents."[117]

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[114] 21 U.S.C. § 355(j)(5)(B)(iv) & (D).

[115] *See generally* Mem. of Law in Supp. of Pls.' Mot. to Exclude in Part the Expert Ops. of Christine Meyer, Ph.D. and Philip Green that Authorized Generics Were Facing Legal Uncertainty, ECF No. 904-1.

[116] *See Teva Pharms. Indus. Ltd. v. Food & Drug Admin.*, 355 F. Supp. 2d 111, 119 (D.D.C. 2004) (upholding FDA's decision to permit authorized generics during the 180-day exclusivity period), *aff'd sub nom. Teva v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005); *Mylan Pharms., Inc. v. Food & Drug Admin.*, No. 04-242, 2005 WL 2411674, at *9 (N.D.W. Va. Sept. 29, 2005) (upholding FDA's denial of a citizen petition seeking to prohibit authorized generics during the 180-day exclusivity period), *aff'd*, 454 F.3d 270 (4th Cir. 2006). These appellate decisions followed a 2004 FDA decision that authorized generics were procompetitive and would therefore be allowed. *See* FDA Response to Mylan and Teva's Citizen Petitions, FDA Docket Nos. 2004P-0075/CP1 & 2004P-0261/CP1 (July 2, 2004), *available at* http://www regulations.gov/#!documentDetail;D=FDA-2004-P-0400-0003. The FDA's upheld ruling was that the marketing of authorized generics should not "be delayed . . . as this marketing appears to promote competition in the pharmaceutical marketplace, in furtherance of a fundamental objective of the Hatch-Waxman amendments." *Id*. at 2.

[117] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* vi (Aug. 2011), https://loadtest ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

Despite the above findings, at deposition, Watson's former CEO, Paul Bisaro, offered inadmissible legal opinions regarding the propriety of authorized generics. For example, he characterized authorized generics as a "loophole" that "in [his] view, [are] used to thwart the provisions of the 180 days of exclusivity . . . [and] should not be allowed during the exclusivity period since Congress created a provision that was designed for an option and the AG circumvents that option."[118] Mr. Bisaro stated that he does not "think it's appropriate" for brand companies to launch authorized generics during the first-filer exclusivity period.[119] He further opined that the "purpose" of the 180-day exclusivity period under the Hatch Waxman Act is to allow generic companies to "recoup" their investment and it would be "very challenging for companies to continue to challenge patents" without full exclusivity.[120] He implied that no-AG agreements are actually consistent with the Hatch-Waxman Act because "the rule was, you got 180 days of exclusivity. [The No-AG] provision protects that."[121]

"Legal opinions, when offered by a non-lawyer lay witness, are both 'incompetent and unpersuasive.'"[122] Accordingly, statements such as the ones Mr. Bisaro made above should be excluded from trial as inadmissible lay opinion under Rule 701. Furthermore, given the findings of the FDA and FTC, such opinions are simply misleading and risk juror confusion under Rule 403. Defendants should not be permitted to argue that authorized generics are anticompetitive or

[118] Robertson Decl. Ex. B, Bisaro Dep. at 29:19-31-22.

[119] *Id.* at 189:24-190:17.

[120] *Id*. at 119:17-120:10.

[121] *Id*. at 120:11-14.

[122] *Park W. Galleries, Inc. v. Glob. Fine Art Registry, LLC*, No. 2:08-CV-12247, 2010 WL 891695, at *2 (E.D. Mich. Mar. 8, 2010) (quoting *United States v. Canipe*, 569 F.3d 597, 603 (6th Cir. 2009)); *accord Town of Lexington v. Pharmacia Corp.*, No. 12-CV-11645, 2015 WL 1321457, at *6 (D. Mass. Mar. 24, 2015) ("It has been observed that witness testimony offering legal conclusion is inadmissible. . . .").

deter generic pharmaceutical companies from challenging patents or launching generic versions of drugs.

### B. Motion No. 18: Purchasers' Motion *in Limine* to Preclude Defendants From Offering Argument or Evidence that Characterizes an At-Risk Launch as "Theft" or "Illegal"

Purchasers respectfully request a ruling that Defendants are precluded from offering any evidence or argument that characterizes an at-risk launch as "theft" or "illegal." Purchasers seek this order because they anticipate that Defendants may attempt to characterize at-risk launches as akin to theft of intellectual property or illegal. This is contrary to law, would mislead the jury, and would be unduly prejudicial.

Under the Hatch-Waxman Act and patent law, once the 30-month stay has expired and the FDA approves its ANDA, a generic is *entitled* to launch at risk without waiting for final judgment in the patent case.[123] The patent holder can prevent such competition only by obtaining an injunction, and to obtain that relief it must show a likelihood of success with respect to both infringement *and* validity.[124] While Purchasers intend to present evidence that Watson would not have incurred patent liability by launching, Defendants should not be permitted to suggest that an at-risk launch is in any way a theft or illegal, as it is not. To suggest otherwise is wrong as a matter of law and would prejudice Purchasers' case.

For the reasons set forth above, Purchasers request that the Court preclude Defendants from offering any evidence or argument that characterizes an at-risk launch as "theft" or "illegal."

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[123] *See* 21 U.S.C. § 355(j)(5)(B)(iii); *Sanofi-Synthelabo v. Apotex, Inc.*, 488 F. Supp. 2d 317, 344 (S.D.N.Y. 2006) (noting that Apotex "is entitled under the Hatch-Waxman Act [to conduct] an at-risk launch in advance of a determination on the merits of its defenses in this litigation that the '265 patent is invalid and unenforceable"); *Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990) (until there is a judicial finding of validity and infringement, the alleged infringer has a "right to compete").

[124] *See Nutrition 21 v. United States*, 930 F.2d 867, 869-70 (Fed. Cir. 1991).

### C. Motion No. 19: Purchasers' Motion *in Limine* to Exclude Argument or Evidence of Risk Aversion to Justify the Reverse Payment

Purchasers respectfully submit this memorandum in support of their motion to preclude Defendants from offering evidence or arguing that their aversion to risk justified any reverse payment in this case. Risk aversion is not a cognizable justification under *FTC v. Actavis*, 570 U.S. 136 (2013), and should therefore be excluded as irrelevant.

A brand's payment to a generic manufacturer to avoid the risk of litigation is precisely what *Actavis* found to be illegal.[125] Defendants claim that the avoidance of litigation uncertainty was procompetitive and not anticompetitive.[126] The Court should preclude Defendants from asserting the very thing that makes their conduct anticompetitive as a justification under the rule of reason.

In *Actavis*, the Supreme Court specifically rejected the possibility that risk aversion could explain or justify a reverse payment:

> The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.[127]

Thus, Defendants should not be permitted here to assert the "relevant anticompetitive harm" to be a procompetitive justification.[128]

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[125] *Actavis*, 570 U.S. at 156 ("Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the ***risk*** of patent invalidation or a finding of noninfringement." (emphasis added)).

[126] *See, e.g.*, Expert Report of Christine S. Meyer, § III.B.1, Jan. 4, 2019, ECF No. 877-4; *id.* ¶ 97 ("Indeed, resolving litigation uncertainty can create direct economic efficiency gains that benefit the settling parties and consumers by encouraging investment. This is evidenced by the fact that investors considered litigation outcome uncertainty in assessing Warner Chilcott's profitability and valuation.").

[127] *Actavis*, 570 U.S. at 157.

[128] *See King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 403-09 (3d Cir. 2015) (repeatedly emphasizing that reverse payments are anticompetitive because they prevent "the risk of competition").

The Court in *Lidoderm*, granted a motion *in limine* similar to this one, explaining that: "Defendants may not argue that the Settlement in and of itself was procompetitive by removing litigation uncertainty *for defendants*."[129]

Evidence of risk aversion should also be excluded as a justification because it does not explain how Warner Chilcott's payments to Watson fostered competition. To be cognizable under the rule of reason, a defendant's proposed justification must establish "some countervailing procompetitive virtue."[130] That is because the rule of reason "focuses directly on the challenged restraint's impact on competitive conditions."[131]

A justification is not cognizable under the rule of reason just because it makes good business sense to Defendants.[132]

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[129] *Lidoderm*, 2018 WL 7814761, at *7; *see also id.* at *6 (proffered justifications "that benefit only the settling parties (and not the market or consumers) are not" considered under rule of reason); *Apotex, Inc. v. Cephalon, Inc.*, Civ. A. Nos. 2:06-cv-2768, 2:10-cv-5164, 2:09-cv-3956, No. 2:09-cv-3820, 2017 WL 2362400, at *5 (E.D. Pa. May 31, 2017) (also granting motion *in limine*: "To the extent that Defendants nonetheless intend to introduce evidence regarding Cephalon's litigation uncertainty, such evidence is inadmissible."); *Cephalon*, 2015 WL 5783603, at *8 (excluding expert opinion in reverse payment case that "reverse payments were made to avoid litigation uncertainty" because the risk of the brand losing infringement litigation is not relevant under *Actavis*); Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating Actavis*, A.B.A. ANTITRUST, Fall 2013, at 20 ("The [Supreme] Court says that payments to avoid even a small risk of competition are antitrust violations. That is reason enough to deny a risk-aversion defense." (footnote omitted)). In arguing their summary judgment motion, Defendants cited *In re Wellbutrin XL Antitrust Litigation Indirect Purchaser Class*, 868 F.3d 132, 167-68 (3d Cir. 2017), for the proposition that risk aversion may be a defense in a reverse payment case. *See* H'rg Tr. at 159-60, Sept. 11, 2019 (Robertson Decl. Ex. C). However, that is not what *Wellbutrin XL* says, and, even if it were, it could not overrule *Actavis*. *Wellbutrin XL* did not address the potential justification of a reverse payment, but rather considered the sufficiency of plaintiffs' evidence of causation. Defendants claimed that a "blocking" patent held by a third party (not the brand's own patent) was a superseding cause of any generic delay. In this context, the Third Circuit held that the fact of the reverse payment standing alone was not sufficient to overcome the evidence that the patent would have prevented the earlier introduction of a generic. The court reasoned that the reverse payment did not necessarily establish the blocking patent to be weak because it may have merely reflected the brand's fear that the generic could launch at risk of infringing the third-party blocking patent, which the brand company did not hold, and thus had no standing to assert. *Wellbutrin* XL, 868 F.3d at 167-70.

[130] *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 459 (1986).

[131] *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 688 (1978).

[132] *See Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1341 (Fed. Cir. 2006) (explaining that the Supreme Court has rejected the argument that anticompetitive conduct "should be excused on the ground that it provided benefits and furthered a public policy unrelated to competition"); *LePage's Inc. v. 3M*, 324 F.3d 141, 163 (3d Cir. 2003) (defense that defendant was merely "act[ing] in furtherance of its economic interests does not constitute the type of business justification that is an acceptable defense to § 2 monopolization"); *Freeman v. San Diego Ass'n of Realtors*, 322 F.3d

Defendants may believe that it made good business sense for Warner Chilcott to pay Watson to avoid the uncertainty of litigation. But payments made to avoid the risk of litigation are precisely what were prohibited by *Actavis*. There is nothing procompetitive about such risk aversion. The Court should preclude Defendants from presenting such evidence or making such arguments.

For the foregoing reasons, Purchasers respectfully request that the Court grant their motion *in limine* to preclude Defendants from introducing evidence or arguing that Warner Chilcott's aversion to risk justified the reverse payment in this case.

### D. Motion No. 20: Purchasers' Motion *in Limine* to Exclude Evidence or Argument that the Reverse Payments Were Not "Large" Compared to Warner Chilcott's Revenue or Profits

Purchasers respectfully submit this memorandum in support of their motion to preclude Defendants from presenting evidence or argument that the reverse payments were not "large" compared to Warner Chilcott's revenue or profits.

Under *Actavis*,[133] Purchasers must prove that Warner Chilcott made a "large" reverse payment to Watson to avoid the risk of competition. Defendants in other cases have argued that

1133, 1152 n.24 (9th Cir. 2003) ("It does not matter that Fallbrook and Valley Center would have operated at a loss in a competitive environment. Their precarious financial situation may have explained their intransigence, but it does not transform it into a viable defense. If there is any argument the Sherman Act indisputably forecloses, it is that price fixing is necessary to save companies from losses they would suffer in a competitive market."); *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1184 (N.D. Cal. 2017) ("While maintaining good business relations with Endo might have been a key goal of Teikoku, Teikoku does not show how that goal has any pro-competitive impact on consumers or on the industry in general, or on any other consideration relevant to a rule of reason analysis. That justification, if true, does nothing to negate the inference (or according to plaintiffs, the actuality) that the payments agreed to by Endo and Teikoku were to delay competition."); *Barr Pharms.*, 572 F. Supp. 2d at 63 n.24 ("Although the Court does not reach the merits of Barr's proffered procompetitive benefits, the Court notes that 'benefits' are only procompetitive when they promote and protect competition, not competitors and when they do not rely on 'the assumption that competition itself is unreasonable.'" (citations omitted)); Am. Bar Ass'n, Antitrust Law Developments (Eighth) 75 (8th ed. 2017) ("Because the rule of reason focuses on anticompetitive effects, factors unrelated to the restraint's effect on competition are generally irrelevant to the analysis.").

[133] *FTC v. Actavis*, 570 U.S. 136.

reverse payments were not large relative to the overall revenue and profit of the brand manufacturer protected by the reverse payment settlement.[134] In this motion, Purchasers seek to preclude Warner Chilcott from making any such argument that the tens of millions of dollars that it paid Watson were not "large" because the payments represent only a small percentage of the Loestrin 24 revenue or profits that Warner Chilcott preserved by making the payments. Such a comparison is contrary to *Actavis and should be precluded.*

*Actavis* establishes two benchmarks for assessing whether a reverse payment is large. First, from the perspective of a brand manufacturer, a reverse payment is "large" if it exceeds the litigation costs that the brand company saved by settling.[135] Second, from the perspective of the generic, the question is whether the payment was "large" enough to induce the generic to abandon its patent challenge and delay its entry into the market.[136] As *Provigil* summarized these requirements, "a reverse payment is sufficiently large if it exceeds saved litigation costs and a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its patent claim."[137]

Here, this Court held that Purchasers satisfied their initial burden because "Plaintiffs have sufficiently alleged that the Agreements were not otherwise justified by 'avoided litigation costs

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[134] *See, e.g.*, Trial Tr. at 113-20, *Walgreen Co. v. Cephalon, Inc.*, No. 09-3956, *Rite Aid Corp. v. Cephalon, Inc.*, No. 09-3820, *Giant Eagle, Inc. v. Cephalon, Inc.*, No. 10-5164, *Apotex, Inc. v. Cephalon, Inc.*, No. 06-2768, (E.D. Pa. June 14, 2017) (opening argument of D. Baldridge, Esq.) (Robertson Decl. Ex. D); *see generally King Drug Co. of Florence v. Cephalon, Inc. (Provigil)*, 88 F. Supp. 3d 402, 416-17 (E.D. Pa. 2015).

[135] *Actavis*, 570 U.S. at 156-57; *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 551 (1st Cir. 2016) ("[T]he size of the reverse payment, particularly as it relates to potential litigation expenses, is central to the antitrust query . . . .").

[136] *Actavis*, 570 U.S. at 153-54 (explaining that a reverse payment "has the 'potential for genuine adverse effects on competition' because "[t]he payment may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market" (quoting *FTC v. Ind. Fed'n of Dentists*, 476 U.S. at 460-61)).

[137] *Provigil*, 88 F. Supp. 3d at 417.

or fair value for services.'"[138] This is consistent with the First Circuit's recognition that *Actavis* "emphasizes . . . the size of the reverse payment, particularly as it relates to potential litigation expenses."[139] Judge Young's jury instructions in *Nexium* likewise defined "large" as a payment that was "at least more" than the brand's saved litigation costs.[140] Other district courts have agreed that a reverse payment may be "large" if it exceeds the brand's saved litigation costs.[141]

While it is ultimately the jury's role to decide whether a reverse payment above litigation costs is sufficiently "large" to induce a generic manufacturer to delay generic entry, courts have specifically rejected comparisons of the payment to the brand's sales or profits. Before *Actavis*, the Eleventh Circuit reasoned in support of its (now obsolete) scope-of-the-patent test for reverse payments that a desire to protect large brand profits could justify "substantial" reverse payments: "When hundreds of millions of dollars of lost profits are at stake, 'even a patentee confident in the

[138] *Loestrin*, 261 F. Supp. 3d at 338 (quoting *Actavis*, 570 U.S. at 156); *see also id.* at 331-22 (comparing allegations of payments made to allegations of litigation costs).

[139] *Loestrin*, 814 F.3d at 551.

[140] *See* Trial Tr. at 35:18-36:2, *In re: Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-02409-WGY (D. Mass. Dec. 3, 2014) (Jury Charge) (Robertson Decl. Ex. E) ("But was the value transferred to Ranbaxy, was that large? Well, it's got to be at least more than the, um, money that they saved by not paying these lawyers -- not our lawyers, but the lawyers who were in on the patent case, and that costs money, substantial money. So the value has to be at least more than that. Whether a payment is 'large' depends upon the specific circumstances of a particular case. As I said, it's got to be at least more than AstraZeneca's reasonably estimated save[d]-litigation costs.").

[141] *In re K-Dur Antitrust Litig., No. 01–cv–1652*, 2016 WL 755623, at *12 (D.N.J. Feb. 25, 2016) (describing plaintiffs' initial burden to show whether "consideration exchanged in the settlement exceeded the estimated cost of litigation"); *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 718 (N.D. Ill. 2016) ("A 'large' payment is anything more than the value of the avoided litigation costs plus any other services provided from the generic to the brand manufacturer."); *Lidoderm*, 74 F. Supp. 3d 1052, 1072 (N.D. Cal. 2014) (holding that allegation that large payments had "no rational connection to, and far exceed, any approximation of the costs of continuing the patent litigation" was sufficient to survive a motion to dismiss); *see also* Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application 2046d6 (4th ed. Supp. 2015) (*Actavis* "does not require evidence of a payment of a particular size, but only a payment in excess of reasonably anticipated litigation costs."); *Id.* ("[A] plaintiff need not plead the precise or even a ballpark value of a no-AG agreement; rather, it must provide a sufficient basis for believing that the value of the agreement exceeds anticipated litigation costs."); *cf. In re Cipro Cases I & II*, 348 P.3d 845, 857 (Cal. 2015) ("[A] plaintiff must establish the amount of the payment, over and above the value of collateral products or services from the generic, also exceeds the brand's anticipated future litigation costs.").

validity of its patent might pay a potential infringer a substantial sum in settlement.'"[142] In overruling this test, the Supreme Court expressly rejected the Eleventh Circuit's reasoning:

> The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.[143]

This makes sense. Because a brand's profits far exceed a generic's, a brand need not pay a "large" portion of its monopoly profits to induce delay. A payment substantially lower than the brand's monopoly profits can significantly impact the finances of the generic and induce it to abandon the patent fight, resulting in anticompetitive effects.

In *Actavis* itself, Solvay (the brand) paid Paddock $12 million, Par $60 million, and Actavis between $19 million and $30 million per year over nine years (between $171 million and $270 million total).[144] AndroGel's total sales over eight of those nine years were in excess of $6 billion.[145] But the fact that the payments from Solvay to the generic defendants were at most 5% of AndroGel's sales at risk over that period was not the issue. Rather, as the Supreme Court stated, "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size,

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[142] *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1313 (11th Cir. 2012) (quoting *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F. 3d 1294, 1310 (11th Cir. 2003)), *rev'd sub nom., FTC v. Actavis,* 570 U.S. 136 (2013).

[143] *Actavis*, 570 U.S. at 157; *see also id.* at 148-49 (declining to "measure the length or amount of a restriction solely against the length of the patent's term or its *earning potential*" (emphasis added)).

[144] *Id.* at 145, 156-57.

[145] *See Pharmaceutical Sales 2006*, Drugs.com, http://www.drugs.com/top200_2006.html (last visited Oct. 17, 2019); *Pharmaceutical Sales 2007*, Drugs.com, http://www.drugs.com/top200_2007 html (last visited Oct. 17, 2019); *Pharmaceutical Sales 2008*, Drugs.com, http://www.drugs.com/top200_2008 html (last visited Oct. 17, 2019); *Pharmaceutical Sales 2009*, Drugs.com, http://www.drugs.com/top200_2009 html (last visited Oct. 17, 2019); *Pharmaceutical Sales 2010*, Drugs.com, http://www.drugs.com/top200 html (last visited Oct. 17, 2019); U.S. Pharmaceutical Sales – 2011, Drugs.com, http://www.drugs.com/stats/top100/2011/sales (last visited Oct. 17, 2019); U.S. Pharmaceutical Sales – 2012, Drugs.com, http://www.drugs.com/stats/top100/2012/sales (last visited Oct. 17, 2019); *U.S. Pharmaceutical Sales – 2013*, Drugs.com, http://www.drugs.com/stats/top100/2013/sales (last visited Oct. 17, 2019).

*its scale in relation to the payor's anticipated litigation costs.*"[146] Further, the Supreme Court held that "[i]f the basic reason" for the brand's payment "is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement."[147] The clear statements from the Supreme Court in *Actavis* preclude any evidence or argument from Defendants that the payment Watson received from Warner Chilcott was small in relation to the size of branded Loestrin 24 sales or similar comparisons.

No opinion supports a legal standard that would permit the jury to conclude that a payment was not large because it was less than the value of the patent monopoly. The court in *Provigil* recognized that a comparison between the payment and the brand's sales does not answer the key question posed by *Actavis* - whether the payment was "large enough to induce the Generic Defendants to stay off the market."[148] Similarly, the *Lidoderm* court granted plaintiffs' motion *in limine* seeking to preclude defendants' evidence and argument at trial that the reverse payments in that case were not large compared the brand companies' profits. The court reasoned that *Actavis* "teaches away from considering at the very least the defendant's profits from the drug at issue."[149] And, in *Aggrenox*, the court rejected comparisons of the reverse payment to the value of the patent as inconsistent with *Actavis,* explaining: "Large reverse payments that are not particularly large in relation to the value of the patent may show confidence in the patent, but if they represent payment to *avoid the risk of invalidation,* then they still run afoul of *Actavis.*"[150]

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[146] *Actavis*, 570 U.S. at 159 (emphasis added).

[147] *Id.* at 158.

[148] *Provigil*, 88 F. Supp. 3d at 417.

[149] *Lidoderm*, 2018 WL 7814761, at *7 ("*Actavis* instructs that 'large' is hinged to anticipated saved litigation costs and its independence from payments for other services.").

[150] *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015).

For the reasons set forth above, Purchasers respectfully request that the Court grant their motion *in limine* to exclude Defendants from offering evidence or argument that the reverse payments in this case were small in comparison to the revenues or profits that Warner Chilcott earned on Loestrin.

### E. Motion No. 21: Purchasers' Motion *in Limine* to Exclude Evidence and Argument That the FTC or the Patent Court "Approved" the Watson Settlement

Purchasers respectfully request that the Court preclude Defendants from introducing evidence or argument that either the FTC or the patent court "approved" the Watson settlement.

In accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), parties must file their pharmaceutical patent litigation settlement with the FTC and DOJ.[151] Warner Chilcott and Watson complied with this provision. They also filed a stipulation of dismissal of their patent litigation that was entered by the District of New Jersey. Both the MMA filing and the stipulation of dismissal appear on Defendants' exhibit lists.[152] In this motion *in limine*, Purchasers ask the Court to preclude Defendants from arguing that either the FTC's failure to take action on the filed settlement agreement or the district court's entry of the stipulation of dismissal constitute "approval" of the reverse payment settlement agreement. Neither the FTC nor the patent court approved the settlement agreement, and any evidence or argument implying such approval would be inaccurate, misleading, irrelevant, and highly prejudicial.[153]

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[151] MMA, Pub. L. No. 108-173, §§ 1111-1118, 117 Stat. 2461-64 (codified at 21 U.S.C. § 355 note).

[152] *See* Defs.' Ex. List at Prelim. Ex. No. DX F-224/WCL0682267 (Robertson Decl. Ex. F) & DX C-445/WCL0109817 (Robertson Decl. Ex. G), Oct. 3, 2019.

[153] *See King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, Nos. 2:06-cv-1797, 2:06-cv-2768, 2016 WL 5928685, at *1-2 (E.D. Pa. Jan. 8, 2016) (defendants prohibited from mentioning FTC and patent court did not act against reverse payment settlement agreements).

### 1. The absence of an FTC challenge to the settlement is irrelevant and substantially more prejudicial than probative.

The FTC has made clear that its inaction on settlements submitted under the MMA does not mean that the FTC has determined that an agreement did not violate the antitrust laws:

> A lack of action by the Commission or its staff with respect to a filed agreement *does not signify an implicit approval of the agreement or a lack of antitrust concern*. In addition, the [Medicare Prescription Drug, Improvement, and Modernization Act of 2003] expressly provides that FTC inaction concerning a filed agreement is not a bar to any later antitrust action. ***Any suggestions by drug companies to courts or others that FTC inaction indicates that the agreement presents no antitrust problem would be inaccurate and improper.***[154]

Thus, any suggestion that the FTC's inaction on the MMA submission indicates the absence of an antitrust violation would be "inaccurate and improper" and not at all probative under Federal Rule of Evidence 401. To the extent that such statements do have any probative value, they would be substantially more prejudicial than probative and should be excluded under Federal Rule of Evidence 403.

The Third Circuit explicitly held in a pay-for-delay antitrust case that "it is erroneous to conclude that the FTC's inaction equates to a determination that the settlement agreement does not run afoul of the Sherman Act."[155] Courts have expressly rejected defendants' attempts to argue that the FTC's failure to object effectively sanctioned the settlement agreement.[156] Any evidence

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[154] *Frequently Asked Questions About Filing Agreements with the FTC Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, Fed. Trade Comm'n (footnote omitted), https://www.ftc.gov/system/files/attachments/competition-policy-guidance/mma_pharmaceutical_agreement_filing_faq_6-6-19.pdf (last visited Oct. 17, 2019) (emphasis added).

[155] *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 263 (3d Cir. 2017); *see also In re High Fructose Corn Syrup Antitrust Litig.*, 295 F.3d 651, 664 (7th Cir. 2002) (lack of prosecution by DOJ and evidence of prior criminal conviction are both equally inadmissible); *In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig.*, 643 F. Supp. 2d 482, 502 (S.D.N.Y. 2009) (excluding testimony of agency inaction because it was irrelevant and would "only serve to confuse the jury").

[156] *Lipitor*, 868 F.3d at 262-63 ("Even if the submission of the settlement agreement to the FTC could create an inference that Wyeth somehow lacked antitrust intent, that intent is not an element of an antitrust claim, and benign intent does not shield anticompetitive conduct from liability").

concerning the FTC's decision not to prosecute Warner Chilcott or take other action regarding its settlements with generic competitors is therefore irrelevant and highly prejudicial.

**2. The patent court's entry of defendants' stipulation of dismissal is irrelevant and substantially more prejudicial than probative**

Any argument that the district court's entry of Defendants' stipulation of dismissal under Federal Rule of Civil Procedure 41, upon the settlement of the patent case, means that the district court "approved" the settlement should likewise be precluded under Fed. R. Evid. 401, 402, and 403.

The ministerial act of entering a voluntary dismissal order under Rule 41(a) is not an endorsement of the settlement underlying the dismissal.[157] Accordingly, the stipulation of dismissal is not probative of whether the underlying settlement agreement unreasonably restrains trade.[158] Consequently, it should be excluded as irrelevant. However, even if the stipulation of dismissal has some slight probative value (which Purchasers do not concede it does), that value would be "substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, [or] misleading the jury."[159] The Court's approval of the stipulation would be likely to unfairly suggest to the jury that the court approved the settlement.[160]

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[157] *See, e.g.*, *SmithKline Beecham Corp. v. Pentech Pharm., Inc.*, 261 F. Supp. 2d 1002, 1008 (N.D. Ill. 2003) (Posner, J.) ("[T]he granting of a motion to dismiss under Rule 41(a)(2) does not imply judicial approval of the underlying settlement agreement. The grant of the motion implies no view of the merits of the agreement and confers no immunities on the settling parties. . . . A settlement agreement that merely motivates the dismissal of a suit is not a judicial order, and the dismissal does not insulate it from legal challenge."); *id.* at 1005 (a district court has "no authority to deny [a] motion to dismiss" under Rule 41, even if the "motion is based on a settlement agreement that may be contrary to public policy as expressed in the antitrust laws"); *see also King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d at 398 (reinstating antitrust claims against two drug manufacturers concerning the anticompetitive effects of a settlement agreement, even though the patent court entered the parties' stipulation of dismissal).

[158] *See Greycas, Inc. v. Proud*, 826 F.2d 1560, 1567 (7th Cir. 1987) (Posner, J.) (prior judgments inadmissible).

[159] Fed. R. Evid. 403.

[160] *See, e.g.*, *Faigin v. Kelly*, 184 F.3d 67, 80 (1st Cir. 1999) ("A lay jury is quite likely to give special weight to judicial findings merely because they are judicial findings."); *Nipper v. Snipes*, 7 F.3d 415, 418 (4th Cir. 1993)

For the foregoing reasons, the Court should exclude any evidence or argument that the FTC or the patent court approved of the Watson settlement.

### F. Motion No. 22: Purchasers' Motion *in Limine* to Preclude Defendants from Referring to the Absence of Lupin or Other Generic Defendants

Purchasers respectfully request an order precluding Defendants from offering evidence or argument to the jury that they have been unfairly targeted or singled out by Purchasers because Lupin and other manufacturers of generic Loestrin 24 are not defendants at trial.

Although Retailer Plaintiffs and End-Payors filed suit against Warner Chilcott, the manufacturer of Loestrin 24, and two generic manufacturers, Watson and Lupin, Purchasers will only be proceeding to trial against Warner Chilcott and Watson. No other manufacturer of generic Loestrin 24 has been a defendant in any of these cases. Warner Chilcott and Watson should be precluded from offering evidence or argument to the jury that they have been unfairly targeted or singled out by Purchasers. Any argument suggesting that Warner Chilcott and Watson were the only ones accused of illegal conduct would necessitate the introduction of evidence of Retailer Plaintiffs' and End-Payor Plaintiffs' settlements with Lupin to show that Lupin and Warner Chilcott were in fact accused of anticompetitive conduct in this case, which Defendants would undoubtedly challenge under Federal Rule of Evidence 408. Moreover, evidence of the Lupin settlements would waste time and create a significant risk of jury confusion.

In addition, the Lupin settlements and the absence of other generic manufacturers at trial are irrelevant to any issue in this case. This case is about Warner Chilcott's enforcement of a fraudulently procured patent against Watson, its sham litigation against Watson, its illegal reverse-

("[J]udicial findings of fact 'present a rare case where, by virtue of their having been made by a judge, they would likely be given undue weight by the jury, thus creating a serious danger of unfair prejudice)); *Greycas, Inc.*, 826 F.2d at 1567 ("[A] jury . . . is apt to give exaggerated weight to a judgment."); *cf. King Drug*, 2016 WL 5928685, at *1 (limiting use of stipulated dismissal at a reverse payment trial "to establish that the challenged settlement agreements ended the Paragraph IV litigation").

payment settlement with Watson and its execution of an anticompetitive product hop. No conduct by any other generic manufacturer could supersede Warner Chilcott's and Watson's liability for agreeing to delay Watson's launch of its ANDA for generic Loestrin 24. Additionally, no conduct by any other generic manufacturer could supersede Warner Chilcott's liability for its decision to wrongfully enforce against Watson a patent that it knew was fraudulently obtained and its decision to discontinue selling Loestrin 24. Indeed, when Lupin was still a defendant in the case, Warner Chilcott submitted expert reports asserting that Lupin could not have obtained FDA approval for its generic Loestrin 24 any earlier than it actually did in 2015.[161] Thus, while an "empty chair" defense may be appropriate where a defendant can argue that an absent defendant was in fact the cause of plaintiff's injury, this is not such a case.

Accordingly, the Court should preclude Defendants from suggesting that they have been targeted or singled out by Purchasers for liability.

### G. Motion No. 23: Purchasers' Motion *in Limine* to Preclude Defendants From Introducing Arguments or Evidence Concerning Michael Johnson's Opinions or Testimony

Purchasers respectfully request an order precluding Defendants from introducing opinions or testimony from Michael Johnson, a former pharmaceutical industry executive who Retailer Plaintiffs and End-Payor Plaintiffs have withdrawn as an expert. Likewise, Defendants and their experts should not be permitted to refer to Mr. Johnson as an expert hired by Purchasers.

Retailer Plaintiffs and End-Payor Plaintiffs retained Mr. Johnson to review and opine on the Asacol Supply Agreement ("ASA") and the Femcon Supply Agreement ("FSA") entered into between Warner Chilcott Company, LLC ("WC") and Lupin Limited and Lupin Pharmaceuticals,

[161] *See* Expert Rept. of Christopher Smith, Feb. 14, 2019, ECF No. 860-16; Expert Rept. of Robert A. Dormer, Feb. 14, 2019, ECF No. 860-4.

Inc. (collectively "Lupin") in 2010. Pursuant to those agreements, Warner Chilcot appointed Lupin to distribute an authorized generic of Asacol and Femcon. These agreements were entered into on October 14, 2010, the same day that Warner Chilcott and Lupin settled patent litigation regarding Loestrin 24. Retailer Plaintiffs and End-Payor Plaintiffs alleged that the ASA and FSA were reverse payments and asserted an antitrust claim against Lupin and Warner Chilcott. Direct Purchaser Plaintiffs did not assert any claims involving the Lupin/Warner Chilcott agreements and did not retain Mr. Johnson.

On January 4, 2019, Mr. Johnson submitted an expert report opining that: (1) WC did not conduct the kind of search for an AG partner that a brand manufacturer typically conducts, and the ASA and FSA do not include the typical terms that brand manufacturers negotiate in such agreements; (2) the financial terms that WC entered into with Lupin are substantially more favorable to Lupin than one would expect in an arms' length AG agreement; (3) the fair value of the ASA is substantially less than the amount WC agreed to pay Lupin under these agreements; and (4) it is unlikely that a brand manufacturer like WC would have been interested in the FSA and, therefore, the entire amount that WC agreed to pay to Lupin for the FSA could be considered an overpayment. Mr. Johnson was deposed on March 21, 2019.

Subsequently, Mr. Johnson was withdrawn as an expert. On June 6, 2019, following their settlement with Lupin, Retailer Plaintiffs and End-Payor Plaintiffs filed a Notice of Intent Not to Pursue the Lupin Reverse Claim Against Defendant Warner Chilcott, Withdrawal of Michael Johnson as an Expert, and Mootness of Certain of Defendants' Pending Motions.[162] Thereafter, the Court denied as moot Defendants' Motion to Exclude Certain Testimony of Michael

[162] ECF No. 971.

Johnson.[163] Thus, the issues on which Mr. Johnson was retained to testify are moot, and Purchasers will not call Johnson to testify at trial.

Defendants are precluded from calling Johnson as a witness absent "exceptional circumstances" because he is a non-testifying expert pursuant to Rule 26(b)(4)(B). However, the adoption of this standard would be consistent with First Circuit law recognizing that, absent a showing of need, a district court is within its discretion in denying an opposing party's efforts to call the other side's expert to testify.[164]

No exceptional circumstances exist in this case. None of Mr. Johnson's testimony that Defendants have designated is unique or testimony that Defendants cannot elicit from their own witnesses and experts. Defendants have designated sound bites from Mr. Johnson's deposition testimony including on life cycle management, co-promotion agreements, reasons why a company may enter into multiple business development agreements in a single day, the negotiation of pharmaceutical deals, and the risk associated with pharmaceutical transactions. Similar testimony on these subjects is available (and is in fact offered) by Defendants' expert Mr. Berneman. Thus, no exceptional circumstances exist in this case which would require Mr. Johnson's testimony.[165]

Additionally, allowing Defendants to selectively pick and choose snippets from Mr. Johnson's testimony would be unfairly prejudicial and cumulative. Defendants appear to have selected sound bites for the purpose of informing the jury that certain Purchasers had an expert

[163] *See* Text Order denying as moot [888] Motion to Exclude Certain Opinions and Testimony of Michael Johnson (June 12, 2019).

[164] *See Jasty v. Wright Medicial Tech.*, 528 F.3d 28, 39 (1st Cir. 2008) (affirming district court's denial of one party's efforts to introduce at trial the deposition of its opponent's damage expert where the opponent did not call the expert to testify at trial and there was no showing of need).

[165] *See Emhart Indus., Inc. v. Home Ins. Co.*, 515 F. Supp. 2d 228, 266 (D.R.I. 2007) (no exceptional circumstances where party's own expert had already opined on the issue).

that they did not call to testify whose testimony is consistent with certain of Defendants' defenses and experts' opinions. While such an argument would be factually incorrect, allowing Defendants to plant such seeds in the jurors' minds would be unfairly prejudicial to Purchasers and should be precluded.[166]

Finally, as to the Direct Purchaser Plaintiffs, Mr. Johnson is not even a non-testifying expert, and admitting his deposition testimony against them would be even more prejudicial than admitting it against the other Plaintiff groups.[167]

In sum, no exceptional circumstances exist here and allowing Defendants to present Mr. Johnson's cumulative testimony to the jury would be unduly prejudicial to Purchasers. Accordingly, Purchasers respectfully request an order precluding Defendants from introducing opinions or testimony from Mr. Johnson.

### H. Motion No. 24: Purchasers' Motion *in Limine* to Preclude Defendants From Introducing Subjective Evidence or Making Argument That They Would Not Have Reached an Alternative Settlement With an Earlier Licensed Entry Date Absent the Alleged Payments

Purchasers respectfully request an order precluding Defendants from introducing subjective evidence or argument that Warner Chilcott and Watson would not have reached an alternative settlement with a licensed entry date earlier than January 2014 absent the large and unjustified payment to Watson (*i.e.* the No-AG, Femring, and Generess deals). Antitrust causation

[166] *See Emhart Indus., Inc.*, 515 F. Supp. 2d at 266 (discussing prejudice caused if opposing party were permitted to call expert and concluding that cumulative and unnecessary testimony did not warrant prejudicing a party); *see also Rubel v. Eli Lilly & Co.*, 160 F.R.D. 458, 462 (S.D.N.Y. 1995) (precluding party from calling expert witness previously retained by the opposing party because of the cumulative nature of the testimony and the "explosive" prejudice that would occur if the expert's prior retention was mentioned before the jury).

[167] *Cf. Lehan v. Ambassador Programs, Inc.*, 190 F.R.D. 670, 672 (E.D. Wash. 2000) ("exceptional circumstances" approach "recognizes certain underlying principles of litigation: that each party is free to choose its expert witnesses to consult with and to exercise its judgment on whether or not to call the expert witness at trial; that expert witnesses once retained remain the witness of the retaining party; . . . and, that the court has the discretion to permit one party to call as a witness at trial *the opposing party's* expert witness when there has been a showing of 'exceptional circumstances'" (emphasis added)).

is guided by objective evidence of how rational economic actors would have behaved but-for the illegal conduct at issue. Subjective, self-serving testimony by Defendants that they would not have acted differently has no place. Moreover, such speculation constitutes improper opinion testimony by a lay witness excludable under Federal Rule of Evidence 701.

**1. Antitrust causation is a matter of objective economic fact, not self-serving subjective beliefs.**

As one of Purchasers' causation theories, Purchasers allege that in the absence of a large payoff by Warner Chilcott to Watson, the parties could have reached an alternative settlement with an earlier licensed entry date as suggested by *Actavis*.[168] This theory of causation is predicated on objective evidence of what rational economic actors would have done in the but-for world.[169] It is not guided by self-serving, subjective speculation that Defendants never could have come to an alternate arrangement under different circumstances. But that is exactly the type of evidence that Defendants plan to adduce at trial.

Both Watson and Warner Chilcott's former CEOs provided self-serving testimony that Defendants would have entered into a settlement with the same entry date even if the consideration between the parties changed.[170] At summary judgment, Defendants seized this testimony to argue

[168] *FTC v. Actavis, Inc.*, 570 U.S. at 158 ("[T]he fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.").

[169] *Lidoderm*, 296 F. Supp. 3d at 1180 n.42 ("[I]n construction but-for world scenarios, there is a presumption of economical rationality." (citation omitted)); *id*. at 1188 ("[Expert] may opine that in his view the parties would have been rationally motivated to agree to settlement allowing Watson early entry by specific dates.").

[170] Robertson Decl. Ex. B, Bisaro Dep. at 153:20-23 ("We would have signed the Loestrin [SLA] whether we signed Generess or not."); *id*. at 177:25-178:3 ("I would have done the deal on Loestrin whether or not we got those [Femring and Generess] deals or not."); *id.* at 245:2–13, 247:5–19 (further claiming Watson would have settled without the No-AG, Generess, and Femring Agreements); Robertson Decl. Ex. H, Decl. of Roger Boissonneault, Feb. 4, 2019, ¶ 20 ("Warner Chilcott would not have agreed to any entry date earlier than the one in the Watson-Warner Chilcott settlement."); *id*. at ¶ 25 ("We would have entered into the Generess agreements or Femring agreement independently of the Loestrin 24 settlement. Similarly, had we not entered into these business agreements, Warner Chilcott would still have entered into the Loestrin 24 settlement agreement with Watson.").

that "[t]here is no evidence that the parties actually would have entered an alternative patent settlement with an earlier entry date."[171] Despite the fact that there *is* such evidence,[172] its supposed absence would be neither controversial nor consequential because this issue is controlled by objective evidence of what rational economic actors would have done.[173]

The Supreme Court's decision in *United States v. Falstaff Brewing Corp.*[174] exemplifies antitrust law's concern with objective, rather, than subjective evidence. The Supreme Court found reversible error in a district court's over-reliance upon executives' self-reported intentions rather than expert and other testimony establishing the objective economic circumstances that drive rational manufacturers' actions.[175] In determining whether Falstaff would likely enter a market, the question was "not what Falstaff's internal company decisions were but whether, given its financial capabilities and conditions in the New England market, it would be reasonable to consider it a potential entrant into that market."[176] In other words, the proper focus should have been on whether "*rational* beer merchants in New England [could conclude] that Falstaff might well build a new brewery to supply the northeastern market," which would have required the court to

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[171] Mem. of Law in Supp. of Defs.' Mot. for Summ. J. 28, ECF No. 858-1. *See also* Defs.' Material in Supp. of Mot. for Summ. J. Dismissing Reverse Payment Claims, Slide 10, ECF No. 1230-14 (arguing there is no evidence that "Warner Chilcott and Watson would have entered an alternative settlement")

[172] Pls.' Resp. to Defs.' Statement of Undisputed Facts ¶ 94, ECF No. 973-1.

[173] *Lidoderm*, 296 F. Supp. 3d at 1190 ("Because this case is set in a but-for world, it is not surprising that no evidence shows that defendants were contemplating anything other than the actual Settlement."); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-MD-02503, 2018 WL 563144, at *21 (D. Mass. Jan. 25, 2018) ("Defendants argue that nothing in the record suggests that 'Impax and Medicis ever discussed or negotiated a licensed entry date earlier than November 2011.' Requiring such evidence, however, would be an almost impossible standard to require of Plaintiffs, given that this is a but-for scenario." (citation omitted)); *id.* at *23 (it "cannot be the standard" that an alternative settlement causation theory "rise[s] and fall[s] solely on whether there is evidence that, essentially, the but-for scenario in question actually occurred").

[174] 410 U.S. 526 (1973).

[175] *Id.* at 537; *see also id.* at 534 (subjective testimony from company insiders is "not necessarily the last word" on antitrust causation).

[176] *Id.* at 533.

"apprais[e] *the economic facts* about Falstaff and the New England market . . . ."[177] Indeed, *Falstaff* emphasized that economic evidence "is the lifeblood of antitrust law," and therefore the most important evidence is the "objective economic facts."[178]

In *Sullivan v. National Football League*,[179] the First Circuit reaffirmed the importance of objective evidence in showing antitrust causation. Sullivan, the then-owner of the Patriots football team, claimed the league's policy disallowing public sale of ownership stock prevented him from selling a minority interest in the Patriots to pay his debts.[180] The First Circuit canvassed the evidence – including Sullivan's expert's opinion, economic evidence, and an analogy to an earlier stock sale of the Boston Celtics basketball team[181] – to examine a hypothetical: could someone in Sullivan's position have sold Patriots stock had the NFL's policy not been in place? The First Circuit held as "a matter of law" that Sullivan's expert "provided enough of a basis . . . to support, in combination with the evidence from other sources, a jury finding" that Sullivan could have sold his Patriots stock if permitted to do so.[182] The expert had testified that a market for Patriots stock existed, and an investment bank had offered an $80 million loan contingent on NFL approval of the stock sale.[183] The First Circuit found this evidence of causation sufficient, not because Sullivan *thought* he could sell some Patriots stock, but because he introduced objective evidence of market conditions that would have enabled someone in his position to have sold stock in the team.[184]

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[177] *Id*. (emphasis added).

[178] *Id*. at 534 n.13.

[179] 34 F.3d 1091 (1st Cir. 1994).

[180] *Id*. at 1103.

[181] *Id*. at 1102, 1105-06.

[182] *Id*. at 1105.

[183] *Id*.

[184] *Id*. at 1104-05.

Here, consistent with causation's objective inquiry, Purchasers have proffered two experts (Dr. McGuire and Dr. Leffler) who have objectively analyzed how reasonable economic actors would have proceeded in the absence of the large and unjustified payment from Warner Chilcott to Watson.[185] For example, Dr. McGuire consulted the parties' financial forecasts to calculate their expected profits from different generic entry dates and determined the range of feasible dates that would "leave[] each firm at least as well off as if there were no settlement."[186] Both Dr. McGuire and Dr. Leffler concluded that reasonable parties in the position of Warner Chilcott and Watson would have compromised on a licensed entry date well before January 2014.[187] Such expert testimony is routine and should be admitted at trial.[188] But subjective, baseless, and self-serving testimony by Defendants as to what they would or would not have done in the but-for world should not be admitted.

**2. Self-serving speculation as to how Defendants would or would not have acted in the but-for world is inadmissible lay witness opinion.**

Beyond the fact that Defendants' subjective statements do not fit an objective causation inquiry, such self-serving statements are also speculative and improper lay witness opinion under Federal Rule of Evidence 701. For example, in *Wilson v. Bradlees of New England, Inc.*, the First

[185] McGuire Report ¶¶ 214-230 (ECF No. 708-6) (determining what "reasonable" pharmaceutical companies would have done in a settlement without a reverse payment); Leffler Report ¶ 47 (ECF No. 708-9) (determining "reasonable alternative settlement entry dates that would have been economically acceptable to the parties absent the alleged anticompetitive payment for delay").

[186] McGuire Report ¶ 224.

[187] Rebuttal Expert Rept. of Thomas G. McGuire, Mar. 12, 2019, ECF No. 860-27, ¶ 122 n.213 ("[R]easonable companies in Warner Chilcott and Watson's respective positions would agree to" an alternate entry date between August 2010 and October 2011.); Leffler Report ¶ 56 ("[U]nder reasonable specifications of the expectations of Warner Chilcott and Watson" the parties would have compromised on a licensed entry date in December 2011 at the latest.).

[188] *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 174 (S.D.N.Y. 2018) (expert could testify that "'it would have been economically rational for both parties' to enter into a no-payment settlement in a but-for world by specific dates"); *Lidoderm*, 296 F. Supp. 3d at 1188 ("[Expert] may opine that in his view the parties would have been rationally motivated to agree to settlement allowing Watson early entry by specific dates.").

Circuit held that a plaintiff's proposed testimony as to how "she would have acted" had a product contained a warning was "properly excluded . . . under Rule 701 as speculative and not based on [plaintiff's] contemporaneous perceptions."[189] Court's routinely exclude litigants from providing self-serving speculation as to how they would or would not have acted in the but-for world.[190] Accordingly, Defendants should be precluded from testifying that they would have acted the same in the but for world as they did in the actual world and would not have acted differently and compromised on an earlier licensed entry date absent the large reverse payment.

For the reasons set forth above, Purchasers request that this Court enter an order precluding Defendants from introducing subjective evidence or argument that Warner Chilcott and Watson would not have reached an alternative settlement with a licensed entry date earlier than January 2014 absent the large and unjustified payment to Watson.

## I. Motion No. 25: Purchasers' Motion *in Limine* to Exclude Argument That Entry Prior to Patent Expiration Was "Early" and a Procompetitive Justification

Defendants should be precluded from arguing at trial that Watson's January 22, 2014 entry was "early" and therefore a procompetitive justification for Defendants' reverse payment. The fact that a reverse payment settlement permits entry before expiration of the patent in litigation is not

[189] 250 F.3d 10, 15 n.8 (1st Cir. 2001).

[190] *See, e.g.*, *Washington v. Dep't of Transp*., 8 F.3d 296, 299-300 (5th Cir. 1993) ("[Plaintiff] attempted to testify as to what he *would have done* had he seen the warning label [concerning vacuum use around explosive vapors] on the Shop Vac vacuum. Because such testimony would not have been based upon [plaintiff's] perception, but upon his self-serving speculation, we hold that the district court did not abuse its discretion in excluding this evidence.") (emphasis in original) (footnote omitted); *Kloepfer v. Honda Motor Co.*, 898 F.2d 1452, 1459 (10th Cir. 1990) (trial court properly excluded "speculative and self-serving statements to the effect that had a different warning been on the vehicle, [plaintiff] would not have allowed her six-year-old son to ride it"); *Kennedy v. Adamo*, No. 02-cv-1776, 2006 WL 8435144, at *5 n.10 (E.D.N.Y. Mar. 29, 2006) ("Even if this case were to go to trial, plaintiff's testimony as to what he would have done had he looked in the rearview mirror would be inadmissible, as it constitutes speculative opinion by a lay witness."); *Messenger v. Bucyrus-Erie Co.*, 507 F. Supp. 41, 43 (W.D. Pa. 1980) (plaintiff's proposed testimony that he would not have been injured if a crane had a back-up light "was a pure conclusion based on speculation, was self-serving, and contained no adequate basis of factual support . . . [and] was not based on evidence of any perceptions of the plaintiff").

a procompetitive justification. *Actavis* itself involved a settlement that permitted entry 65 months before expiration of the brand manufacturers' patent.[191] The Supreme Court took "this fact as evidence that the agreement's 'anticompetitive effects fell within the scope of the exclusionary potential of the patent.'"[192] But it did "not agree that that fact, or characterization, can immunize the agreement from antitrust attack."[193]

The Supreme Court further explained that a defendant "may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason."[194] Defendants may be able to justify the payment by proving that it was not in fact made for delay. But evidence that the reverse payment settlement permitted entry prior to patent expiration does not provide any such non-delay procompetitive explanation. It merely restates the "scope of the patent" standard that *Actavis* discarded. Accordingly, evidence or argument that licensed entry before patent expiration is procompetitive misstates the law and risks substantial juror confusion under Rule 403. Such evidence and argument should be excluded at trial. At a minimum, subjective statements by defense witnesses that they believed the settlement provided "early entry" should be excluded because such statements "impermissibly 'involve[ ] beliefs about the strength of the patents and the outcome of the patent litigation'" that necessarily place attorney advice at issue.[195]

### J. Motion No. 26: Purchasers' Motion *in Limine* to Preclude Argument or Testimony that the No-AG Provision is an Exclusive License

[191] *FTC v. Actavis, Inc.*, 570 U.S. at 145.

[192] *Id*. at 147 (citation omitted).

[193] *Id*.

[194] *Id*. at 156.

[195] *Lidoderm*, 2018 WL 7814761, at *7 (granting in part a motion *in limine* to exclude argument that entry prior to patent expiration was "early" (alteration in original) (citation omitted)).

Defendants may try to reassert their argument that the No-AG provision in the Watson settlement agreement is reasonable because it constitutes a mere exclusive patent license that is permitted by the Patent Act. Like every other court to evaluate this argument, this Court previously rejected this "exclusive license" argument in denying Defendants' motion to dismiss in this case.[196] This argument should not be re-raised at trial.

Moreover, Defendants should be precluded from even characterizing the No-AG provision as an "exclusive license." The Settlement and License Agreement expressly terms Watson's license as "non-exclusive."[197] The No-AG provision did not stop Warner Chilcott from selling branded Loestrin 24 under the '394 patent, and Watson did not receive any rights to enforce the '394 patent. There is simply no basis to call the No-AG provision an "exclusive license."[198]

## III. MOTIONS RELATED TO PRODUCT HOP

### A. Motion No. 27: Purchasers' Motion *in Limine* to Exclude Dr. Meyer's Testimony on the Existence of Other Oral Contraceptives, Which Cannot Disprove Coercion[199]

[196] *Loestrin*, 261 F. Supp. 3d at 333 ("If some particular transfer of money would be unlawful—for whatever reason—its unlawfulness is not cured merely because the value is transferred in the form of exclusive licenses instead of cash, irrespective of whether the grant of an exclusive license would otherwise be valid." (quoting *Aggrenox*, 94 F. Supp. 3d at 245)); *see also* Phillip Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 2046f2 (Supp. 2019) ("Some no-authorized-generic agreements take the form of an 'exclusive license' given to the generic to commence production at some future date. Given the delay, however, such agreements do not constitute a 'license' at all. At most they are agreements to license production at some future time.").

[197] Robertson Decl. Ex. J, Settlement and License Agreement ¶ 6, WCL2539153-165 ("WCCI grants to Watson a *non-exclusive*, fully paid-up, worldwide, royalty-free, irrevocable license . . . .") (emphasis added).

[198] At a minimum, Defendants should be precluded from characterizing the No-AG as "authorized" or "permissible" under patent law. *Lidoderm*, 2018 WL 7814761, at *8 (holding defendants "should not describe [a no-AG] as 'authorized' or otherwise permissible under patent law because that is not a question for the jury").

[199] Many of the arguments in this section were raised in earlier briefing on Plaintiffs' Motion to Exclude Opinions and Testimony of Drs. Christine S. Meyer, Mark Robbins, and Melissa Schilling Regarding Lack of Anticompetitive Effect from Product Hop. ECF No. 875 (motion); ECF No. 877-2 (brief in support) ("P. Daubert Br."); ECF No. 1006-1 (brief in opposition) ("D. Daubert Opp. Br."); ECF No. 1101-2 (reply brief) ("P. Daubert Reply Br."). At the *Daubert* hearing, the parties announced their agreement to defer oral argument on that motion and re-raise the issues through motions *in limine*. Hearing Tr., at 2 (Sep. 12, 2019), ECF No. 1253.

Dr. Meyer, Defendants' economist, relies on the existence of oral contraceptives—other than Loestrin 24 and Minastrin—to opine that the product hop did not deprive patients of the relevant economic choice. In so doing, Dr. Meyer fundamentally misapplies the proper test for "coercion." To the extent that coercion is an element of a product-hop claim, it concerns not the lack of choice between *any* alternatives, but the lack of choice to *remain on Loestrin 24*. Any opinion and testimony that Loestrin 24 patients could still pick between *other contraceptives* is therefore irrelevant and misleading, and the Court should exclude it as such.

In attempt to rebut any evidence of coercion, Dr. Meyer dedicates a section of her report to conclude that "Consumers Had Many Choices."[200] This is based on her findings, in four subsections, that contraceptive "options" existed *other than* Loestrin 24 and Minastrin at the time of the product hop in mid-2013. In her first subsection, she uses market data to find that "[m]any other OCs were available before and after the alleged time period of Minastrin 24's launch and Warner Chilcott's phasing out of Loestrin 24."[201] In her next subsection, she uses switching data to find that "as of Q2 2013, when Warner Chilcott halted production of Loestrin 24, Loestrin 24 patients had *many choices of products to which they could possibly switch*."[202] In her next two subsections she says "prescribers could have written a prescription for . . . another therapy entirely that has similar indications" and "pharmacists were able to offer patients . . . a therapeutic alternative [to Loestrin 24 or Minastrin that] they saw fit."[203] She uses these facts to conclude that "there is no evidence . . . that consumers had fewer options available to them" as a result of the

[200] Responsive Expert Rept. of Christine S. Meyer, Feb. 14, 2019, ECF No. 877-5, ¶¶ 179-88.

[201] *Id.* ¶¶ 180-84.

[202] *Id.* ¶ 186 (emphasis added).

[203] *Id.* ¶¶ 187-88.

product hop.[204] These arguments mimic those that Defendants briefed and argued as part of their motion for summary judgment.[205]

The Court should exclude Dr. Meyer's testimony as to "coercion." In a product hop case, the alleged anticompetitive effect is the reduction of the prescription base—here, Loestrin 24—available for automatic generic substitution.[206] The purpose of finding coercion is to determine that such a reduction in the prescription base occurred not as a result of competition on the merits, but from a lack of consumer choice.[207] Thus, the *relevant* lack of choice here is the choice to stay on Loestrin 24. That lack of choice—between staying or switching— occurs *regardless* of what alternative products were available for a consumer to pick. Accordingly, Dr. Meyer's testimony that Loestrin 24 patients could have switched or did switch to drugs other than Minastrin does not tend to disprove coercion. It is irrelevant.

The case law makes abundantly clear that depriving consumers the choice *between staying or switching* is the relevant test of coercion. In *Namenda*, the finding of coercion depended on the ability of doctors and patients to choose "whether the benefits of switching to once-daily Namenda

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[204] *Id.* ¶ 203.

[205] Defs.' Summ. J. - Product Hopping Slides at 18, Sept. 11, 2019, ECF No. 1229-2 (depicting +150 contraceptives available for patients to switch between); *see also id.*, at 23 (stating that after the product hop "patients switched away from Loestrin 24 to OCs other than Minastrin").

[206] *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 655 (2d Cir. 2015) ("*Namenda*") ("Forcing patients to switch" to a non-AB rated product would "prevent generic substitution" and result in "'few to no prescriptions' left for which generics would be eligible to compete."); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 423 (D. Del. 2006) ("*Tricor*") (Defendants' switch to non-AB rated drug meant that generic manufacturers "cannot provide generic substitutes" which is their "cost-efficient means of competing in the pharmaceutical drug market"; "[s]uch a restriction on competition, if proven, is sufficient to support an antitrust claim in this case."); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 684 (E.D. Pa. 2014) (finding harm to competition from defendants' hard switch because "generic tablets are not AB-rated and thus may not be substituted" for the product that patients are switched to).

[207] *Namenda*, 787 F.3d at 655 ("Because Defendants' forced switch 'through something other than competition on the merits[ ] has the effect of significantly reducing usage of rivals' products and hence protecting its own . . . monopoly, it is anticompetitive.'" (quoting *United States v. Microsoft Corp.*, 253 F.3d 34, 65 (D.C. Cir. 2001))); *Tricor*, 432 F. Supp. 2d at 421-23.

XR would *outweigh the benefits of adhering to twice-daily therapy using less-expensive generic IR (or perhaps lower-priced Namenda IR).*"[208] The court held that "[b]y removing Namenda IR from the market prior to generic IR entry, Defendants sought to deprive consumers *of that choice*."[209] Depriving consumers of the choice to remain on their existing formulation meant the defendants "could avoid competing against lower-cost generics based on the merits of their redesigned drug . . . ."[210] Even though the evidence showed that as many as 20% of doctors/patients expected to choose a product other than the reformulated product,[211] *Namenda* found coercion because the defendant deprived consumers of the choice to stay *on their current formulation* (which was soon to go generic).[212]

Similarly, in *Tricor*, Judge Jordan recognized that in any product redesign case, such as a product hop, the relevant harm is consumers purchasing a product different than what they otherwise would have purchased.[213] Absent evidence of coercion, courts will presume that the actual choice of purchase was the result of competition on the merits, not punishable by antitrust law.[214] In a product hop case, where the anticompetitive harm results from impairing automatic generic substitution, the relevant inquiry is whether patients were deprived of the choice to stay on

[208] 787 F.3d at 655 (emphasis added).

[209] *Id.* (emphasis added).

[210] *Id.*

[211] *Id.* at 654 ("Defendants' hard switch was expected to transition 80 to 100% of Namenda IR patients to XR prior to generic entry").

[212] *Id.* at 655.

[213] *Tricor*, 432 F. Supp. 2d at 421; *id.* at 422 (citing *Microsoft Corp.*, 253 F.3d at 58).

[214] *Id.* at 421 ("If consumers are free to choose among products, then the success of a new product in the marketplace reflects consumer choice, and antitrust should not intervene . . . ." (internal quotation marks and citation omitted)).

the current formulation that would be subject to automatic substitution.[215] Judge Jordan held that coercion existed, and thus antitrust inquiry into the merits of the redesign warranted, because "consumers were not presented with *a choice between fenofibrate formulations*. Instead, Defendants allegedly prevented *such a choice* by removing the old formulations from the market while introducing new formulations."[216]

Even in cases finding a lack of coercion, courts recognize that the relevant choice is whether consumers can remain on the existing formulation. In *Doryx*, the Third Circuit held that "there were no patent cliffs on the horizon" and there was "no evidence of consumer coercion, because generics 'had already entered the market at the time of defendants' product reformulation'"—patients thus did not need to switch away.[217] In *Walgreen*, as this Court recognized, "[t]he brand manufacturer never removed Prilosec from the market, and thus never eliminated consumer choice."[218]

Left unchecked, Defendants would make the coercion inquiry a superficial one, attempting to hoodwink the jury into believing that no anticompetitive harm could result because Loestrin 24 patients could "choose" *between Minastrin and other drugs*. But the existence of that "choice" is not relevant and would blatantly mislead the jury. The patients here *had already chosen Loestrin 24* and thus the relevant question is whether patients could choose whether the benefits of switching "outweigh the benefits of adhering to [Loestrin 24]."[219] Warner Chilcott prevented that

[215] *Id.* at 422-23 ("That opportunity [of providing patients generics through AB-substitution] has allegedly been prevented entirely by Defendants' allegedly manipulative and unjustifiable formulation changes.").

[216] *Id.* at 422 (emphasis added).

[217] *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 440 (3d Cir. 2016) (citation omitted).

[218] *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 353 (D.R.I. 2017); *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008).

[219] *Namenda*, 787 F.3d at 655.

choice regardless of whether patients could or did switch to alternatives other than Minastrin. The existence of those alternatives cannot disprove coercion and would mislead the jury, so Defendants should be prevented from offering evidence and testimony about them.

### B. Motion No. 28: Purchasers' Motion *in Limine* to Exclude Dr. Meyer's Testimony That Consumers Retained the Option to Stay on Brand Loestrin 24—Testimony That Has No Evidentiary Support

Recognizing that Dr. Meyer's reliance on the existence of other drugs is irrelevant, Defendants also seek to offer her testimony that patients had the choice *to remain on Loestrin 24* even after the product hop. As Plaintiffs explained in their earlier *Daubert* briefing, there is no evidentiary basis for Dr. Meyer to opine that such a choice existed.[220]

It is undisputed that Warner Chilcott discontinued sales of Loestrin 24 by August 2013, five months before generic entry in January 2014.[221] Dr. Meyer even agrees with the Purchasers' expert finding that Warner Chilcott expected inventory to be depleted by October 2013.[222] Nevertheless, she states (1) "there is no evidence that Warner Chilcott recalled or withdrew Loestrin 24 from the marketplace" or from the Orange Book, (2) that "Warner Chilcott did not engage in the fabrication of safety concerns regarding Loestrin 24[,]" and (2) that there was "still inventory [of Loestrin 24] in the market" until March 2014.[223] She then concludes that "in the time period of August through October 2013 (and longer), consumers had *more*, not fewer, choices . . . ."[224]

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[220] P. Daubert Br. at 8-9.

[221] ECF No. 877-5 ¶ 160.

[222] *Id.* ("Warner Chilcott's internal documents projected that Loestrin 24 Fe could remain in stock through mid-October." (citing McGuire Rep. ¶ 59)).

[223] *Id.* ¶¶ 160-63.

[224] *Id.* ¶ 160 (emphasis added).

Dr. Meyer's conclusion that discontinuing Loestrin 24 *increased* choice is mere *ipse dixit*; it is completely divorced from any evidentiary support. Indeed, the IQVIA data on which she relies shows that nearly all patients were forced to switch away from Loestrin 24—more than 98% of Loestrin 24 prescriptions switched away in the five months leading up to generic entry (July 2013: 365,449; December 2013: 5,742).[225] Dr. Meyer is merely relying on the existence of *some* supply—less than 2%—to conclude that "consumers had more . . . choices . . . ."[226] But that is not a sufficient basis to say consumer choice *increased*.

In *Namenda*, the court recognized that about 3% of the original formulation's supply would still be available even after discontinuance.[227] But that fact was not relevant or material to the court's determination that the withdrawal was coercive because the relevant inquiry concerns availability to the marketplace, not an extremely small minority of it.[228] Accordingly, there was no *increase* in consumer choice, but a *decrease*.[229]

In finding that consumers had *more* choices after Loestrin 24's discontinuance, Dr. Meyer is seeking to mislead the jury to believe the marketplace still had Loestrin 24 available.[230] This

[225] ECF No. 877-5 Ex. R12 (relying on IMS data, n/k/a IQVIA); Defendants' Statement of Disputed Facts in Response to Plaintiffs' Additional Statement of Material Undisputed Facts at 21 ¶ 263, Dec. 11, 2018, ECF No. 648-1 (admitting that from July 2013 to December 2013, Loestrin 24 prescriptions fell from 365,449 to 5,742).

[226] ECF No. 877-5 ¶ 160.

[227] *Namenda*, 787 F.3d at 648 ("Defendants estimated internally that less than 3% of current Namenda IR users would be able to obtain IR through" a special distribution channel established by defendants even after IR discontinued.).

[228] *Id.* (even with 3% of Namenda IR remaining "available to a limited number of patients, Defendants' actions effectively withdrew Namenda IR from the market" and constituted a '"hard switch' or 'forced switch'").

[229] *Id.* at 655 ("By removing Namenda IR from the market prior to generic IR entry, Defendants sought to deprive consumers of . . . choice.").

[230] *See* ECF No. 877-5 ¶ 188 (stating "physicians had and still have many options to prescribe to their patients, including, . . . Loestrin 24"; "pharmacists were able to offer patients . . . Loestrin" despite the product hop).

lacks any evidentiary support—indeed her own data contradicts her. Rule 702 prevents experts from offering such *ipse dixit* testimony, and the Court should exclude it as such.[231]

### C. Motion No. 29: Purchasers' Motion *in Limine* to Preclude Drs. Meyer, Robbins, and Schilling from Testifying That the Fact of Loestrin 24 Generic Entry Disproves Any Anticompetitive Effect—Testimony That Lacks Fit and Reflects an Unreliable Methodology

In addition to opining that the product hop did not reduce choice, Dr. Meyer also opines that the product hop did not impair Loestrin 24 generic competition.[232] Drs. Robbins and Schilling also attempt to draw the same conclusion.[233] But none of these experts use a reliable methodology. Instead, they find no impairment to generic competition based merely on the fact that Loestrin 24 generics entered and made sales. That test has been rejected as a matter of law—it does not provide a sufficient basis for these experts to conclude no harm to competition occurred.

#### 1. Drs. Meyer, Robbins, and Schilling conclude Loestrin 24 generic competition was not impaired based solely on the fact that their profitable entry was not completely foreclosed.

Dr. Meyer bases her conclusion that Loestrin 24 generic competition was not impaired based *solely* on the fact that Loestrin 24 generics entered and made sales.[234] She refers to evidence that "a total of 7 generic versions of Loestrin 24 launched between January 2014 and June 2017;"[235] that the first generic entrant promoted the product when it was the only generic on the market; and

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[231] *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.").

[232] ECF No. 877-5 ¶ 198 (opining that no evidence shows product hop was "anticompetitive or otherwise suppressed generic competition"); *see Namenda*, 787 F.3d at 648 (after establishing coercion, plaintiffs burden is to show product hop "impeded competition" after which the burden shifts to defendants to justify the harm).

[233] Expert Rept. of Mark S. Robbins, Jan. 4, 2019, ECF No. 877-7, ¶ 118 ("discontinuation of Loestrin® 24 did not impair" competition); Expert Rept. of Melissa A. Schilling, Feb. 14, 2019, ECF No. 877-10, ¶ 115 ("the 'hard switch' from Loestrin 24 to Minastrin 24 in no way suppressed generic competition").

[234] ECF No. 877-5 ¶¶ 170-78.

[235] *Id.* ¶ 173.

that "generics were capable of seizing the opportunity to make sales and, in fact, did so."[236] She goes on to state that "[t]he phasing out of Loestrin 24 production did not block or prevent patients from specifying to doctors the specific branded generic that they wanted to be prescribed;"[237] that a prescription for a particular branded generic can be substituted with an different generic; that "*[t]his substitution* is not prevented by the phasing out in Loestrin 24 production;"[238] and that even if the product hop foreclosed automatic generic substitution with the branded prescription base, that "does not foreclose the generic's ability to sell their product."[239]

Dr. Robbins also concludes that Loestrin 24 generic competition was not impaired based *solely* on the fact that generics were still able to obtain FDA approval and profitably launch. In one section of his report, he refers to the FDA approval of Loestrin 24 generics and states that "[t]he fact that nine different manufacturers sought and obtained FDA approval of nine different ANDA products to Loestrin® 24 demonstrates that the discontinuation of Loestrin® 24 did not impair the successful FDA approval of generic alternatives."[240] In another section, he opines about the lack of anticompetitive effect due to the ability of these generics to launch and make sales.[241]

Lastly, Dr. Schilling concludes that the product hop "in no way suppressed generic competition," citing to Dr. Meyer's report that "7 generics of Loestrin 24 have entered beginning in January 2014" and finding that generic sales grew over time.[242]

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[236] *Id.* ¶¶ 171, 174.

[237] *Id.* ¶ 175.

[238] *Id.* ¶ 176 (emphasis added). Of course, Purchasers do not allege and need not prove that pharmacy substitution *between generics* was foreclosed; this case is about impeding pharmacy substitution for a base of patients whose prescriptions were forcibly switched away to a non-substitutable product months before generic entry.

[239] *Id.* ¶ 177.

[240] ECF No. 877-7 ¶ 118; *see also id.* ¶¶ 115-18.

[241] *Id.* ¶ 133 ("The success of the Loestrin® 24 generics and their ability to compete is evidenced by the significant growth in sales over the past four years."); *see also id.* ¶¶ 125-33.

[242] ECF No. 877-10 ¶ 115.

In sum, all three experts draw a conclusion that the product hop did not impair Loestrin 24 generic competition. They do not draw any comparison to a "but-for" world, showing that generic manufacturers could compete as effectively for sales with or without the product hop occurring. Instead, they all base their conclusion solely on what actually occurred and solely on the fact that Loestrin 24 generics profitably launched.

**2. As a matter of law, the fact of profitable entry cannot disprove a finding of anticompetitive effect.**

Defendants' methodology—concluding no competitive impairment based on the product hop not completely foreclosing profitable entry—is unreliable.

The test that all three experts employ is contrary to law. Every court to address the issue has rejected such a test that asks whether competition was totally and completely foreclosed.[243] To establish an anticompetitive effect, "it is not necessary that all competition be removed from the market."[244] Competitors need not be barred "from all means of distribution," if they are barred "from the cost-efficient ones."[245] Thus, "[t]he test is not total foreclosure," but whether "the challenged practices . . . 'bar a substantial number of rivals *or severely restrict the market's ambit*.'"[246]

[243] *See Loestrin*, 261 F. Supp. 3d at 349, 351 ("For there to be an antitrust violation, generics need not be barred 'from all means of distribution" (quoting *Namenda*, 787 F.3d at 656)); *Suboxone*, 64 F. Supp. 3d at 683 ("complete foreclosure is not the standard"); *Tricor*, 432 F. Supp. 2d at 423 ("If it were true that an antitrust plaintiff had to show that competition were completely foreclosed, then Defendants' argument might have merit. However, that is not the correct legal standard.").

[244] *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005).

[245] *Microsoft Corp.*, 253 F.3d at 64.

[246] *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 403 (3d Cir. 2016) (emphasis added) (quoting *Dentsply*, 399 F.3d at 191); *see also In re Asacol Antitrust Litig.*, 233 F. Supp. 3d 247, 256 (D. Mass. 2017) ("Illegal product hopping—the introduction of a new product by a monopolist in combination with exclusionary conduct that *either severely restricts the market's ambit* or bars a substantial number of rivals—is anticompetitive." (emphasis added)).

In *Tricor*, just as is the case here, the generics were "able to market their own branded versions of the old TriCor formulations," and profitably did so.[247] That fact could not negate an anticompetitive effect, given the allegation that the product hop denied the generics the cost-efficient means of competing—AB-substitution—for the prescription base that defendants moved to the new formulation.[248] Courts in other product hop cases, including this Court, have held as a matter of law that the fact of profitable generic entry does not negate the anticompetitive effect; no court has held otherwise.[249]

None of these experts opine that the product hop somehow did not negatively affect AB-rated substitution—the process by which generics cost-efficiently compete. Dr. Meyer points to Amneal's generic Loestrin 24 sales and promotional efforts, but she fails to opine—because she cannot truthfully or reliably opine—that this competition was as effective as that generated by AB-substitution.[250] Dr. Robbins points to the generics' ability to get favorable formulary tier placement, but fails to opine—because he cannot do so truthfully or reliably—that this generated competition as effective as AB-substitution.[251] Nor do any of these experts even opine about what effect (or not) the product hop had on total Loestrin 24 prescriptions available for generic substitution. Indeed, Dr. Meyer admits this failure.[252]

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[247] *Tricor*, 432 F. Supp. 2d at 416, 423.

[248] *Id.* at 423.

[249] *Loestrin*, 261 F. Supp. 3d at 349, 351 (rejecting defendants' contention that the product hop cannot cause an anticompetitive effect where "generic versions of Loestrin 24 have since entered the market and have been profitable"); *Asacol Antitrust Litig.*, 233 F. Supp. 3d at 256; *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2017 WL 3967911, at *13 (E.D. Pa. Sept. 8, 2017); *Namenda*, 787 F.3d at 656; *Tricor*, 432 F. Supp. 2d at 423.

[250] ECF No. 877-5 ¶ 171.

[251] ECF No. 877-7 ¶¶ 123-24.

[252] Robertson Decl. Ex. K, Meyer Dep. at 246-57 (stating that she did not take into account how many Loestrin 24 prescriptions would have been available before generic entry absent the product hop, and that she does not recall her analysis taking into account the difference between Loestrin 24 prescriptions before and after the product hop).

At bottom, in attempt to rebut Plaintiffs' proof of anticompetitive effect, these experts are relying only on data showing what the state of competition *actually was*, without analyzing what *would have been*.[253] Worse, they rely only on one fact: that Loestrin 24 generic entry was not completely foreclosed. As a matter of law, that fact cannot establish what these experts are concluding.[254] Since they offer *no* basis to show the product hop failed to restrict the market's ambit, there is "too great an analytical gap" for Drs. Meyer, Robbins, Schilling to reliably conclude that Loestrin 24 competition was not impaired.[255]

### D. Motion No. 30: Purchasers' Motion *in Limine* to Exclude Drs. Meyer and Schilling From Testifying About What the Law Is or Should Be

Both Drs. Meyer and Schilling violate the "black-letter law that it is not for witnesses to instruct the jury as to applicable principles of law, but for the judge."[256]

In two sections of her report, Dr. Meyer attempts to interpret and explain antitrust law and its application to product hopping cases. Under one section, titled "Legal Precedent in Alleged 'Product Hop' Cases,"[257] she relies on only *one* case—the district court's summary judgment ruling in *Doryx*—to state her "understanding" that a "brand manufacturer has no legal obligation to facilitate generic competition by keeping an older version of a branded product in the

[253] *In re Mushroom Direct Purchaser Antitrust Litig.*, No. 06-0620, 2015 WL 5766930, at *4 (E.D. Pa. Aug. 20, 2015) (expert cannot reliably rebut a showing of anticompetitive harm by using *only* data about what in fact occurred (the actual world, with the anticompetitive conduct)).

[254] *Bailey v. Allgas, Inc.*, 148 F. Supp. 2d 1222, 1245 (N.D. Ala. 2000) (excluding expert opinion that a "purported high rate of return, by itself, established market power" which was "contrary to the law"), *aff'd*, 284 F.3d 1237 (11th Cir. 2002).

[255] *Gen. Elec. Co.*, 522 U.S. at 146; *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1057 (8th Cir. 2000) (in light of "deficiencies in the [expert's] foundation," the "resulting conclusions were 'mere speculation'" (citation omitted)).

[256] *Nieves–Villanueva v. Soto–Rivera*, 133 F.3d 92, 99 (1st Cir. 1997) (internal quotation marks, alteration, and citation omitted).

[257] ECF No. 877-5 ¶¶ 151-54.

marketplace."[258] She further quotes Judge Diamond's policy arguments against holding manufacturers liable for product hopping.[259] In another section, she states what she believes is necessary to "warrant antitrust scrutiny."[260] According to Dr. Meyer "[t]he introduction of new products and withdrawal of older generation products is not anticompetitive" and there must be additional conduct "that 'coerces' consumers to switch to the new product . . . ."[261]

While Dr. Schilling does not state what the law is, she aggressively contends what the law should be. Without providing any limiting principle or example of when a product hop could be anticompetitive, she advocates for a *per se* legality standard, criticizing the law for even subjecting product hopping to rule of reason scrutiny. Throughout her report she makes bombastic claims that "to regulate what is and is not sufficiently innovative . . . is an inappropriate use of the court system"[262]; that holding companies liable for hard switching "would signal a major breakdown in the free-market economy"[263]; and that "such a rule would be antithetical to how businesses operate (and anticompetitive); it would demand that one company subsidize a rival."[264]

These statements of the law, or of what the law should be, have no place before the jury. For one thing, they are wrong. For example, despite Dr. Meyer's contention, no court has held

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[258] *Id.* ¶ 151.

[259] *Id.* ¶ 153 ("In addition, Judge Diamond goes on to state '[the generic manufacturer's] theory [that the Defendant's reformulation of Doryx delayed generic competition] also risks slowing or even stopping pharmaceutical innovation. The prospect of costly and uncertain litigation every time a company reformulates a brand name drug would likely increase costs and discourage manufacturers from seeking to improve existing drugs.'" (alterations in original)).

[260] *Id.* ¶ 145.

[261] *Id.* ¶¶ 145-46.

[262] ECF No. 877-10 ¶ 15.

[263] *Id.* ¶ 103.

[264] *Id.* ¶ 20; *see also id.* ¶¶ 102-03.

that conduct in addition to a hard switch is necessary to "warrant antitrust scrutiny."[265] And despite Dr. Schilling's claims, coercive product hopping is what prevents the operation of a free-economy—that is why antitrust law condemns it.[266] Their statements of "markedly incorrect law" require exclusion under Rule 702.[267]

For another thing, "[i]t is well-established that experts may not testify as to what the law requires or testify as to the governing law."[268] "[E]ach courtroom comes equipped with a 'legal expert,' called a judge, and it is his or her province alone to instruct the jury on the relevant legal standards."[269]

### E. Motion No. 31: Purchasers' Motion *in Limine* to Exclude Dr. Robbins From Testifying That Warner Chilcott's Product Hop Is "Routine" Conduct by Pharmaceutical Companies, Which Is Irrelevant

Dr. Robbins is not an economist, but an industry consultant.[270] His report details "many examples of successful pharmaceutical products reflecting incremental innovation,"[271] including previous product launches by Warner Chilcott, to establish "the routine nature in which pharmaceutical manufacturers introduce new products and discontinue others as part of their

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[265] *Namenda*, 787 F.3d 638, 654 (2nd Cir. 2015) (the "hard switch crosses the line from persuasion to coercion and is anticompetitive"); *Tricor*, 432 F. Supp. 2d at 422 (defendants sufficiently coerce patients "by removing the old formulations from the market while introducing new formulations").

[266] *Namenda*, 787 F.3d at 654–55 ("[T]he market can determine whether one product is superior to another only so long as the free choice of consumers is preserved." (internal quotation marks and citation omitted)).

[267] *Herbert v. Lisle Corp.*, 99 F.3d 1109, 1117 (Fed. Cir. 1996) ("We encourage exercise of the trial court's gatekeeper authority when parties proffer, through purported experts, not only unproven science, . . . but markedly incorrect law.").

[268] *Withrow v. Spears*, 967 F. Supp. 2d 982, 999 (D. Del. 2013); *see also Gomez v. Rivera Rodriguez*, 344 F.3d 103, 115 (1st Cir. 2003) (recognizing impermissibility of expert "testimony that articulates the ultimate principles of law governing the deliberations of the jury" (quoting *Specht v. Jensen*, 853 F.2d 805, 807-10 (10th Cir. 1988) (en banc))).

[269] *Mushroom*, 2015 WL 5766930, at *2 (quoting *Burkhart v. Wash. Metro. Area Transit Auth.*, 112 F.3d 1207, 1213 (D.C. Cir. 1997)).

[270] ECF No. 877-7 ¶ 5.

[271] *Id.* at ¶¶ 49-88.

broader strategies around portfolio and life-cycle management."[272] He uses that as a basis to conclude that Warner Chilcott's product hop here is not anticompetitive because "Warner Chilcott's actions of launching Minastrin and discontinuing Loestrin 24 are consistent with this routine and competitive industry practice."[273] This analysis lacks fit and is misleading.

To prove Warner Chilcott's product hop produced an anticompetitive effect, Purchasers' burden is to show the combination of withdrawing Loestrin 24 and introducing Minastrin in the context of generic substitution laws was coercive and impaired competition.[274] No amount of comparing Warner Chilcott's conduct to *other* "routine" industry practices tends to rebut such a showing of anticompetitive effect *here*.[275] Despite raising this in earlier briefing, Defendants have offered no response to Plaintiffs' argument that Dr. Robbins' analysis is not a substitute for economic analysis and should not be presented to a jury.[276] The Court should exclude this testimony under Rules 702 and 403.

### F. Motion No. 32: Purchasers' Motion *in Limine* to Exclude Drs. Meyer and Schilling From Testifying That Warner Chilcott's Product Hop Is Similar to Conduct of Companies Outside Pharmaceutical Industry, Which Is Irrelevant

Even further astray than Dr. Robbins, Drs. Meyer and Schilling provide examples of beneficial "incremental innovation" *in other industries*. The Court should exclude this testimony under Rules 702 and 403.

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[272] Rebuttal Expert Rept. of Mark S. Robbins, Apr. 4, 2019, ECF No. 877-9, ¶ 90.

[273] *Id.*

[274] *Loestrin*, 261 F. Supp. 3d at 354.

[275] Many restraints that were formerly ubiquitous in particular industries are today well recognized as producing an anticompetitive effect. *See, e.g.*, *Goldfarb v. Va. State Bar*, 421 U.S. 773, 781 & 783 (1975) (state bar's minimum attorney fee schedules); *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 684 (1978) ("traditional" method of selecting engineers).

[276] P. Daubert Reply Br. at 10.

Dr. Meyer likens Warner Chilcott's hard switch to "creative destruction" tactics used in movie rental, photography, and transportation industries that produced no anticompetitive effects.[277] Dr. Schilling discusses stories about beverage brands, laundry detergents, video game consoles, and Apple Computers that purportedly illustrate the importance of "incremental innovation"[278] and further explains many instances outside the pharmaceutical industry where "[d]iscontinuation of old versions of products is an important part of the process of innovation."[279]

This testimony is highly misleading. It suggests to the jury that to find Warner Chilcott liable for its hard switch in the pharmaceutical industry is to also condemn the practices of some of America's favorite brands, such as Apple Computers for "discontinu[ing] its old iPhone models when it releases a newer model." The economic circumstances are radically different here, which these experts utterly ignore.

By relying on examples outside this industry, Drs. Meyer and Schilling ignore "'the unique characteristics of the pharmaceutical market,' including state generic drug substitution laws and the cost-efficiencies they create."[280] To analogize Warner Chilcott's conduct in the pharmaceutical industry to manufacturers' conduct in other industries runs afoul of the fundamental legal maxim that the "antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue."[281]

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[277] ECF No. 877-5 ¶ 146.

[278] *E.g.*, ECF No. 877-10 ¶ 42 (Coca-Cola); *id.* at ¶¶ 83-85 (laundry detergents); *id.* at ¶ 67 (Apple products); *id.* at ¶ 122 (Nintendo).

[279] ECF No. 877-10 ¶ 108 ("For example, Apple Computers discontinues its old iPhone models when it releases a newer model, usually every year."); *id.* at ¶ 129 ("All car brands, from Honda to BMW, are expected to continue to develop and introduce changes"); *id.* "[O]ur leading food manufacturers continue to offer new flavors, ingredients and packaging.").

[280] *In re Loestrin 24 Fe*, 261 F. Supp. 3d at 351 (quoting *Namenda*, 787 F.3d at 655-56)

[281] *Id.* at 352 (quoting *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004)).

Just like Dr. Robbins' "routineness" opinion, none of Dr. Meyer's and Dr. Schilling's testimony about other industry practices will assist the jury in determining whether the product hop here coerced consumers and impaired Loestrin 24 generic competition. The Court should exclude their testimony.

### G. Motion No. 33: Purchasers' Motion *in Limine* to Exclude All Testimony, Including That of Drs. Meyer, Robbins, and Schilling, That the Withdrawal of Loestrin 24 Was "Procompetitive"

The Court should exclude any testimony that purports to claim that withdrawing Loestrin 24 was associated with procompetitive benefits.

Lay witnesses cannot claim that any aspect of the product hop was "procompetitive" (or "not anticompetitive"), because such legal and economic conclusions require the special skill or knowledge of an expert to render.[282]

As for the experts, while they may be permitted to testify as to a procompetitive benefit, they "cannot simply cite procompetitive benefits in the abstract . . . ."[283] "[M]erely offering a rationale for [the challenged conduct] will not suffice; the record must support a finding that the [challenged conduct] . . . does indeed have a pro-competitive effect."[284]

Drs. Meyer, Robbins, and Schilling violate this rule. They all offer mere *theory* as to why a withdrawal of a product *in general* "could" be procompetitive good business practice. For example, they rely on the fact that simplifying a product lineup "could" allow for certain

[282] *Oster v. Huntington Bancshares Inc.*, No. 15-cv-2746, 2017 WL 3208620, at *8 (S.D. Ohio July 28, 2017); *U.S. Bank Nat'l Ass'n v. PHL Variable Life Ins. Co.*, 112 F. Supp. 3d 122, 138 (S.D.N.Y. 2015); *Lone Mountain Processing, Inc. v. Bowser-Morner, Inc.*, No. 2:00-cv-00093, 2005 WL 1894957, at *18 (W.D. Va. Aug. 10, 2005).

[283] *In the Matter of Impax Labs., Inc.*, No. 9373, 2019 WL 1552939, at *35 (F.T.C. Mar. 28, 2019), *appeal docketed*, No. 19-60394 (5th Cir. Jun. 7, 2019).

[284] *Graphic Prods. Distribs. v. ITEK Corp.*, 717 F.2d 1560, 1576 (11th Cir. 1983); *O'Bannon v. NCAA*, 802 F.3d 1049, 1072 (9th Cir. 2015) (concluding what while "a restraint that broadens choices [is] procompetitive . . . . we fail to see how the restraint at issue in this particular case . . . widens recruits' spectrum of choices").

efficiencies.[285] But none opine that Warner Chilcott actually realized any efficiencies from withdrawing Loestrin 24.

Dr. Meyer does quote deposition testimony that says, in the abstract, that simplifying a product lineup could be efficient. But that testimony says nothing about whether Loestrin 24's withdrawal resulted in any efficiencies. As such, Dr. Meyer merely concludes that "[t]o the extent" such efficiency gains were realized, "those are procompetitive benefits."[286]

Neither she nor any expert attempts to calculate the "extent" these hypoethical efficiencies came to fruition. In short, they provide *absolutely no factual or analytical basis* to claim any efficiencies *actually* flowed from Loestrin 24's withdrawal before generic entry. Court should preclude them from opining that Loestrin 24's withdrawal was procompetitive.[287]

### H. Motion No. 34: Purchasers' Motion *in Limine* to Exclude Testimony That Minastrin Increased Patient Compliance—Testimony That Has No Evidentiary Support

The Court should exclude any testimony that purports to claim that Minastrin's chewability increased patients' compliance with their birth control regimen. For example, Dr. Meyer, an economist, claims that "[p]atient compliance is another issue that Minastrin 24 helped address . . .

[285] ECF No. 877-5 ¶ 189; ECF No. 877-10 ¶¶ 102-03; ECF No. 877-7 ¶ 81 ("discontinuing older versions of products can help an innovator efficiently use its detailing resources"); *see also* ECF No. 877-4 ¶¶ 190-92.

[286] ECF No. 877-4 ¶¶ 190, 192.

[287] *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict."); *Smith v. Jenkins*, 732 F.3d 51 (1st Cir. 2013) (expert's failure to draw on sufficient case evidence amounts to speculation that should be excluded); *Carrozza v. CVS Pharmacy, Inc.*, 391 F. Supp. 3d 136, 145 (D. Mass. 2019) (expert's failure to draw on case evidence amounted reduces conclusions "to mere assumptions, speculation[,] and guesswork" that "must be excluded"); *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 171-72 (S.D.N.Y. 2018) (expert's attempt to conclude what "could" occur amounts to "unsupport[ed] speculation cloaked as expertise").

."[288] Dr. Nakajima, an OB/GYN, opines that chewability "could" lead to increased patient compliance.[289]

Such statements are pure invention. They lack any evidentiary support, and amount to mere speculation. Indeed, April Mitchell—Warner Chilcott's marketing manager from Warner Chilcott's first chewable launch (Femcon) through Minastrin's development—unequivocally testified several times that no evidence supports a claim that a chewable birth control aids patient compliance.[290] Nor did any data exist to support a claim that chewing a birth control pill is more convenient than swallowing it whole.[291]

Lacking any evidentiary basis or personal knowledge, the Court should exclude any testimony that purports to claim Minastrin's chewability increased patient compliance.[292]

### I. Motion No. 35: Purchasers' Motion *in Limine* to Exclude Evidence or Testimony That FDA Concluded Minastrin Was an Improvement Over Loestrin 24.

Defendants have previously plucked statements from Minastrin's FDA summary review in attempt to claim Minastrin conferred a patient benefit. For example, during the summary judgment hearing, they highlighted two sentences: (1) "This chewable tablet product offers an alternative oral dosage form to COC users who may have difficulty swallowing whole tablets"; (2) "By providing a new method of use, the proposed product will expand the therapeutic options for women who cannot or will not swallow a whole COC tablet but wish to use a COC with an iron

[288] ECF No. 877-4 ¶ 191.

[289] Robertson Decl. Ex. L, Expert Rept. of Steven T. Nakajima, ¶¶ 80-81.

[290] Robertson Decl. Ex. M, Mitchell Dep. at 364:4-6 (May 16, 2018) ("we could never promote on compliance because we have no data to support that"); *see also id.* at 417-19.

[291] Robertson Decl. Ex. N, Mitchell Dep. at 467-68 (June 18, 2018).

[292] *Diggs v. Citigroup, Inc.*, 551 Fed. Appx. 762, 765 (5th Cir. 2014) ("[A]n expert's opinion should not be admitted if it does not apply to the specific facts of the case."); *Smith*, 732 F.3d at 68; *Carrozza*, 391 F. Supp. 3d at 145.

supplementation for prevention of pregnancy."[293] Defendants went so far as to claim this approval document meant "Warner Chilcott proved to the FDA that Minastrin would benefit patients."[294] These statements, and any testimony interpreting them, are inadmissible.

First, the statements are inadmissible hearsay. Defendants are offering them for their purported truth, and no hearsay exception applies.[295]

Second, none of Defendants' witnesses have personal knowledge under Rule 602 to interpret the FDA's statements, which on their face come nowhere near suggesting that Warner Chilcott "proved" anything to the FDA about any purported "benefit." While Dr. Nakajima, Defendants' medical expert, relies on the FDA document in his report, he only does so to say that "the FDA found Minastrin and Loestrin 24 to be bioequivalent."[296] He has not relied on the FDA's summary review to infer a patient benefit conferred by Minastrin.

Third, the statements are inadmissible under Rule 403. They misleadingly suggest that a component of the alleged unlawful conduct—the approval and launch of Minastrin—had the imprimatur of a government agency. Defendants furthermore are misleadingly suggesting that Warner Chilcott "proved" to an impartial expert the medical superiority of Minastrin, when in reality the approval only means the drug is safe and effective at preventing pregnancy, just like Loestrin 24.

### J. Motion No. 36: Purchasers' Motion *in Limine* to Preclude Evidence and Testimony That Absent a Violation, Warner Chilcott Would Have Marketed Minastrin—Evidence That Cannot Rebut Purchasers' Injury or Offset Purchasers' Damages.

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[293] Defs.' Summary J. Product Hopping Presentation, at 28 (Sep. 11, 2019), ECF No. 1229-2.

[294] *Id.*

[295] *Bartlett v. Mut. Pharm. Co.*, No. 08-CV-358-JL, 2010 WL 3092649, at *1 (D.N.H. Aug. 2, 2010).

[296] Robertson Decl. Ex. L ¶ 79.

Defendants may seek to introduce evidence or argument that, had Warner Chilcott not impaired or delayed Loestrin 24 generic competition, patients would have purchased branded Minastrin instead of generic Loestrin 24.[297] Defendants claim such evidence rebuts causation/injury or offsets Purchasers' damages. But under any potential scenario at trial, well-established law prohibits Defendants from using Minastrin's launch to deprive Purchasers of injury or damages.

First, Minastrin's launch *is part of the unlawful conduct*. Courts, including this one, consistently hold that the *combination* of introducing a reformulated product (Minastrin) and withdrawing the prior product (Loestrin 24) constitutes an unlawful product hop.[298] While each individual act in isolation may not be unlawful, the *combination* of the two produces "the dual effect" of forcing patients to switch and causing anticompetitive harm.[299] It is hornbook law that a proper analysis of injury and damages removes the unlawful conduct from the "but-for world."[300] Thus, if the jury finds the product hop unlawful, the law requires the jury to consider injury and damages in a world in which *both* Minastrin's launch and Loestrin 24's withdrawal would not have occurred.

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[297] *See, e.g.*, Reply Mem. of Law in Supp. of Defs.' Mot. for Summary J. ("Reply Br."), ECF No. 1055 at 42 (July 8, 2019).

[298] *Namenda*, 787 F.3d at 653-54; *In re Loestrin 24 Fe Antitrust Litig*., 261 F. Supp. 3d at 354.

[299] *Namenda*, 787 F. 3d at 659; *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d at 351.

[300] *See, e.g.*, Mark A. Allen, Robert E. Hall & Victoria A. Lazear, *Reference Guide on Estimation of Economic Damages*, in Reference Manual On Scientific Evidence, Federal Judicial Center, National Research Council of the National Academies ("Reference Manual") at 425, 432 (2011) ("the analysis considers the difference between the plaintiff's economic position if the harmful event had not occurred and the plaintiff's actual economic position"), available at https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf; *Steward Health Care Sys., LLC v. Blue Cross & Blue Shield of R.I.*, 311 F. Supp. 3d 468, 512 (D.R.I. 2018) (Smith, C.J.) (but-for world consists of "a reasonable offense-free world as a yardstick for measuring what, hypothetically, would have happened 'but for' the defendant's unlawful activities"(quoting *LePage's Inc.*, 324 F.3d at 165)); *Procaps S.A. v. Pantheon Inc.*, 141 F. Supp. 3d 1246, 1288 (S.D. Fla. 2015) ("the but-for world (i.e., absent the allegedly anticompetitive agreement")), *aff'd*, 845 F.3d 1072 (11th Cir. 2016).

Defendants cannot seek to include Minastrin's launch in the but-for world by arguing it constitutes only one aspect of the unlawful scheme. Courts universally prohibit defendants from dismantling the elements of a single course of conduct that, taken together, produces an anticompetitive effect.[301] Indeed, the district court in *Suboxone* on three separate occasions rejected the defendants' arguments that antitrust injury cannot result from the introduction of a new product, where, as here, the product's introduction was combined with other conduct (such as removal of the original formulation) which contributes to an "overall effect" of coercing consumers and impeding competition.[302] In *Asacol*, the court on summary judgment accepted that the plaintiffs' product hop theory "would require the Defendants to engage in some conduct that they did not engage in," namely, keeping the tablet formulation on the market *and not introducing the reformulated capsule*.[303] Where there is a single violation with multiple aspects, a proper but-for world removes the entire violation.[304]

Nor may Defendants include Minastrin in the but-for world by claiming that they could have lawfully marketed it. Antitrust scrutiny requires, for purposes of injury and damages, that a

[301] *Namenda*, 787 F.3d at 654 ("noting that when an antitrust conspiracy involves multiple acts, '[t]he character and effect of [the] conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole'" (quoting *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962))).

[302] *Suboxone*, 64 F. Supp. 3d at 679-85; *Suboxone*, 2017 WL 3967911, at *9; *Suboxone*, 2017 WL 4910673, at *9 ("[W]hen a monopolist combines product improvement with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, the conduct is anticompetitive under the Sherman Act.").

[303] *In re Asacol Antitrust Litig.*, 323 F.R.D. 451, 487 (D. Mass. 2017) (holding that absent the unlawful conduct, defendants "would be selling a version of Asacol 400mg with DBS instead of DBP, but no capsule"), *rev'd and remanded on grounds relating only to class certification*, 907 F.3d 42 (1st Cir. 2018).

[304] *Apotex, Inc. v. Cephalon, Inc.*, 321 F.R.D. 220, 236 (E.D. Pa. 2017) (the hypothetical but-for world is one "characterized by the absence of the . . . challenged practices"); *Blades v. Monsanto Co.*, 400 F.3d 562, 569 (8th Cir. 2005) (but-for world is "free of the restraints and conduct alleged to be anticompetitive"); *see also LePage's Inc.*, 324 F.3d at 166 (but-for world does not "segregate and attribute a fixed amount of damages to any one act" where "the theory was not that any one act in itself was unlawful, but that all the acts taken together showed a § 2 violation").

court reject a defendant's "I could have done it legally" argument.[305] If a violation is found, courts hold the unlawful conduct is removed from the but-for world entirely and antitrust violators are "foreclosed from challenging causation . . . on the basis that it could have achieved the same result through lawful means."[306]

Second, even if the jury does not find the product hop violated antitrust law, Minastrin's launch *still* has no lawful place in the jury's consideration of injury or damages. If the jury concludes that Warner Chilcott unlawfully obtained or enforced the patent, or made a reverse payment, Purchasers' injury from that conduct would have occurred as early as 2009, when the first generic Loestrin 24 was approved, long before Warner Chilcott began marketing Minastrin in mid-2013.

Accordingly, for Defendants to rebut injury or offset damages, they must argue that, in the but-for world, Warner Chilcott would have launched Minastrin years earlier than it actually did. But the law precludes Defendants from re-jiggering a but-for world to conveniently accelerate Minastrin's launch. It is well-settled that a but-for world is one "characterized by the absence of

[305] Scholars refer to defendants' arguments as "the trap of the Irrelevant Hypothetical," which is "the fallacious proposition that any time one can construct a counterfactual hypothetical in which (a) the facts are changed such that there is no antitrust violation, yet (b) the plaintiff still suffers damage similar to the injury it actually suffered as a result of the violation, there is no antitrust injury." Ronald W. Davis, *Standing on Shaky Ground: The Strangely Elusive Doctrine of Antitrust Injury*, 70 Antitrust L.J. 697, 725 n.103 (2003).

[306] *Va. Vermiculite, Ltd. v. W.R. Grace & Co. – Conn.*, 156 F.3d 535, 540 (4th Cir. 1998) ("even if Grace lawfully could have donated the lands to HGSI without the nonmining agreements, it is foreclosed from challenging causation simply on the basis that it could have achieved the same result through lawful means"); *Irvin Indus., Inc. v. Goodyear Aerospace Corp.*, 974 F.2d 241, 245 (2d Cir. 1992) ("The possibility that [defendant] might have submitted a lawful bid, and, if so, the same damage might have resulted, cannot in and of itself negate causation as a matter of law."); *Lee-Moore Oil Co. v. Union Oil Co. of Cal.*, 599 F.2d 1299, 1302 (4th Cir. 1979) ("the fact that [the defendant] might have caused the same damages by a lawful cancellation of the contract is irrelevant"); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 648 n.16 (E.D. Mich. 2000) ("[t]o accept Defendants' argument, the Court must also accept the argument that there can never be an antitrust violation if the antitrust defendant can posit an argument that it could have lawfully done the same thing it is accused of doing collusively. The Court finds these arguments unavailing").

the . . . challenged practices"[307]; "the but-for scenario differs from what actually happened *only with respect to the harmful act*"[308] and "hold[s] every other feature of the actual world *constant*."[309] Minastrin's launch does not constitute the unlawful conduct relating to the unlawful patent procurement or enforcement, or to the reverse payments. With respect to those violations, the law requires that Minastrin's launch date be held constant. An antitrust violator is not permitted to escape the consequences of its unlawful conduct by speculating that it might have altered other aspects of its conduct to erase those consequences.[310]

In sum, under no circumstances may the jury properly consider Defendants' evidence or argument that, absent the unlawful product hop, Warner Chilcott would have nevertheless marketed Minastrin. If the jury finds the product hop unlawful, Minastrin's launch—part of the unlawful conduct—must be removed from the but-for calculus entirely. Nor may Defendants,

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[307] *Apotex*, 321 F.R.D. at 236; *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1055 (8th Cir. 2000) (defining "a but-for market," as "free of the restraints and conduct alleged to be anticompetitive" (quoting *Concord Boat Corp. v. Brunswich Corp.*, 21 F. Supp. 2d. 923, 927 (E.D. Ark. 1998))).

[308] Reference Manual, *supra*, at 432 (emphasis added).

[309] Am. Bar Ass'n, Proving Antitrust Damages 89 (3d ed. 2017); *In re Qualcomm Antitrust Litig.*, 328 F.R.D. 280, 310 (N.D. Cal. 2018) ("Federal and state cases alike" support propositions that a but-for world would maintain same, lawful business strategies used in actual world.); *In re: Disposable Contact Lens Antitrust*, 329 F.R.D. 336, 419 (M.D. Fla. 2018) (accepting plaintiffs' expert's statement that "[a] properly defined 'but for' world is one in which all aspects of the actual world remain unchanged except for the effects *caused* by the restraint of trade at issue") (emphasis in original); *White v. NCAA*, No. CV 06-0999-RGK(MANx), 2006 WL 8066803, at *6 (C.D. Ca. Oct. 19, 2006) ("In the proper but for world Plaintiffs correctly assume that all forms of aid, and specifically non-athletic aid, that are currently irrelevant to the question of [the grant in aid cap at issue], remain constant and hence irrelevant."); *see, also* Phillip E. Areeda (late) & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶ 392b (4th Edition 2013-2019)("the 'but for' condition is the profit that would have been earned had the violation not occurred, but *all other economic conditions remained the same*" (emphasis added)).

[310] *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 49-50 (1st Cir. 2013) (upholding damages despite "no evidence that PMG doctors would have prescribed those lower-cost alternative drugs but for Pfizer's conduct"; "The damages inquiry does not allow a defendant to benefit from the scope of its wrongdoing. . . . '[D]oubts should be resolved against the wrongdoer.'" (quoting *BCS Servs., Inc. v. Heartwood 88, LLC*, 637 F.3d 750, 759 (7th Cir. 2011))); *Ocean Spray Cranberries, Inc. v. PepsiCo, Inc.*, 160 F.3d 58, 63 (1st Cir. 1998); *In re Visa Check/Mastermoney Antitrust Litig.*, 192 F.R.D. 68, 85 (E.D.N.Y. 2000) (rejecting hypothetical reduced volume of transactions as "immaterial"), *aff'd*, 280 F.3d 124 (2d Cir. 2001); *In re Skelaxin (Metaxalone) Antitrust Litig.*, No. 1:12-md-2343, 2014 WL 2002887, at *5 (E.D. Tenn. May 15, 2014) ("courts and juries will not be forced down the rabbit hole of hypothetical issues antitrust violators may raise to minimize their liability").

with respect to the patent-related and reverse-payment violations, speculate that Warner Chilcott would have accelerated Minastrin's launch *several years earlier*. The settled law is that the but-for world must hold constant everything except the unlawful conduct and that all doubts must be resolved against the antitrust violator. The Court should therefore preclude Defendants from offering Minastrin's launch to rebut injury or offset Purchasers' damages as to any liability theory. The evidence is irrelevant.

### K. Motion No. 37: Purchasers' Motion *in Limine* to Exclude Cumulative and Duplicative Testimony From Drs. Meyer, Robbins, and Schilling Regarding Anticompetitive Effect or Procompetitive Justifications Relating to the Product Hop

Drs. Meyer, Robbins, and Schilling, offer duplicative opinions concerning the product hop. While they have different backgrounds, they all seek to offer the same or similar reasons that the product hop was not anticompetitive, but procompetitive. For example, as explained above, they all say that the product hop did not impair generic competition for the simple reason that Loestrin 24 generics actually entered the market and made sales. They also proffer testimony that introducing new products is beneficial to society and is routinely done alongside the withdrawal of older generation products. Moreover, they seek to testify about the purported procompetitive effects associated with Minastrin's introduction and Loestrin 24's withdrawal.

Defendants should not be permitted to offer this duplicative testimony from *three* experts, especially since they are all rebutting just *one* of Purchasers' experts (Dr. McGuire). It is standard practice in complex litigation such as this for courts to exercise discretion and exclude such duplicative expert testimony under Rules 403 and 611(a).[311] The testimony of Drs. Meyer's,

[311] *E.g.*, *Campbell Indus. v. M/V Gemini*, 619 F.2d 24, 28 (9th Cir. 1980) (district court had discretion to exclude cumulative expert testimony); *In re Testosterone Replacement Therapy Prods. Litig.*, No. 14-cv-1748, 2017 WL 1836443, at *20 (N.D. Ill. May 8, 2017) ("[P]laintiffs may intend to offer testimony by multiple expert witnesses on particular topics. . . . The Court does not intend to permit this by either side absent a prior showing of good cause").

Robbins', and Schilling is inadmissible for the many reasons stated above. But to the extent their product hop testimony survives, Defendants should be limited to offering just one of the three at trial.

## IV. MOTIONS REGARDING PATENT ISSUES

### A. Motion No. 38: Purchasers' Motion *in Limine* to Exclude Argument or Evidence of Settlements to Establish the Strength of the '394 Patent

Purchasers respectfully submit this memorandum in support of their motion to exclude argument or evidence by Defendants that various Warner Chilcott settlements of patent litigation establish the strength of the '394 patent.

Defendants' exhibit list and arguments at summary judgment suggest that Defendants intend to offer evidence at trial that the '394 patent was strong because other companies that Warner Chilcott sued for infringing that patent settled with Warner Chilcott. For instance, in their motion for summary judgment, Defendants claim that a 2006 settlement of patent litigation by Bayer (the "2006 Settlement") "establish[es] the strength of the '394 patent."[312] Such use of settlements to establish the merit of the settled claims is explicitly prohibited by Federal Rule of Evidence 408. And, even if it were not, evidence related to such settlements should be excluded under Federal Rule of Evidence 403 because it is not relevant to this case and any probative value would be substantially outweighed by the danger of confusion, prejudice, undue delay, and waste of time. Accordingly, the Court should preclude any evidence or argument by Defendants that any patent settlement establishes the merit of Warner Chilcott's claims based on the '394 patent.

[312] Mem. of Law in Support of Defs.' Mot. for Summ. J. ("SJ Br."), ECF No. 858, at 21. That litigation concerned Bayer's Yaz contraceptive, and Defendants assert that, under the license agreed to as part of the Bayer settlement, Bayer has paid more than $100 million to Warner Chilcott. SJ Br. at 21 (claiming "royalties on sales of Yaz and related products . . . result[ed] in more than $100 million in total payments from 2006-2014"). Defendants have also identified other settlements of patent litigation in their exhibits and summary judgment papers. *See, e.g.*, SJ Br. at 29 (referencing Mylan's stipulations in the settlement of its patent litigation with Warner Chilcott).

**1. Rule 408 prohibits the use of settlements to prove the merit of the underlying litigation.**

Federal Rule of Evidence 408 provides that evidence of settlement agreements and their negotiation "is not admissible – on behalf of any party – either to prove or disprove the validity or amount of a disputed claim."[313] The rule is based on two rationales: (1) that such evidence is irrelevant "since the offer may be motivated by a desire for peace rather than from any concession of weakness of position"; and (2) that it promotes "the public policy favoring the compromise and settlement of disputes."[314]

As a result, in this Circuit, "the fact of settlement cannot be taken as any admission" because "a settlement is born of compromise," and a settlement does not "entail judicial acceptance of any position taken by a [party to the agreement]."[315] Based on these twin purposes, courts in this Circuit have held that "Rule 408 bars the admission of a settlement agreement to prove the validity or invalidity of a claim or its amount," a prohibition which "applies equally to settlement agreements between a defendant and a third party and between a plaintiff and a third party."[316]

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[313] Fed. R. Evid. 408(a).

[314] Fed. R. Evid. 408 advisory committee's note. *See McInnis v. AMF, Inc.*, 765 F.2d 240, 247 (1st Cir. 1985) (explaining that courts exclude "evidence of settlement offers" in order to "promote a public policy favoring the compromise and settlement of claims" and rule out evidence "of questionable relevance on the issue of liability or the value of a claim").

[315] *RFF Family P'Ship, LP v. Ross*, 814 F.3d 520, 530 (1st Cir. 2016) (excluding settlement evidence under Rule 408).

[316] *Portugues-Santana v. Rekomdiv Int'l*, 657 F.3d 56, 63 (1st Cir. 2011); *see also McInnis*, 765 F.2d at 247 (a settlement between one litigant and a third party is "clearly" barred by Rule 408, as the "policies underlying the exclusionary rule are equally applicable to such a situation"); *Bouret-Echevarria v. Caribbean Aviation Maint. Corp.*, 784 F.3d 37, 46 (1st Cir. 2015) ("[i]nformation regarding settlement offers remains inadmissible" under Rule 408); *Cook v. CTC Commc'ns Corp.*, 2007 WL 3252829, at *5-6 (D.N.H. Oct. 31, 2007) (ruling "evidence of the settlement negotiations and agreement" inadmissible under, *inter alia*, Rule 408); Fed. R. Evid. 408 advisory committee's note ("The protections of Rule 408 cannot be waived unilaterally because the Rule, by definition, protects both parties from having the fact of negotiation disclosed to the jury.").

Accordingly, Rule 408 precludes Defendants' reliance on their settlements of other patent cases to attempt to establish the merit of the claims asserted in those cases as to the '394 patent.

**2. Defendants' reliance on settlements should be excluded as unduly prejudicial under rule 403.**

Even if Rule 408 did not prohibit the use of settlements to establish the merit of the '394 patent, the settlements should be precluded under Rule 403. This rule allows courts to "exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."[317] Here, any probative value of the settlements is substantially outweighed by the risk of prejudice, confusion, and misleading the jury, as well as delay and wasting time.

As this Court concluded in *Uniloc USA v. Microsoft*, "whatever relevance" the settlement of a patent litigation may have, it will be "substantially outweighed by the unfair prejudice . . . and juror confusion that would likely result from these collateral issues" and must therefore be excluded under Rule 403 (in addition to Rule 408).[318] The introduction of settlements of other cases would require mini-trials regarding the various settlement negotiations to establish the reasons for settling and the basis for the statements to which the parties agreed.[319] The issues surrounding the other cases would in all likelihood become a significant part of any trial and would inevitably lead to confusion of the issues before the Court, mislead the jury, needlessly extend

[317] Fed. R. Evid. 403.

[318] *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F. Supp. 2d 147, 159 (D.R.I. 2009) (Smith, J.); *see also Galarneau v. Merrill Lynch, Pierce, Fenner & Smith Inc.*, 504 F.3d 189, 205-06 (1st Cir. 2007) (affirming district court's exclusion of settlement-related evidence under Rules 403 and 408).

[319] *Galarneau*, 504 F.3d at 206 (admitting evidence of settlement discussions "would likely require testimony from the attorneys as to the motivations behind the proposed . . . language and [defendant's] refusal to adopt it"); *RFF Family P'ship*, 814 F.3d at 530.

what is already expected to be a lengthy trial, and unduly waste the Court's limited time and resources.

In addition, the introduction of the 2006 Settlement would be unduly prejudicial. Defendants have repeatedly emphasized that Bayer ultimately paid Warner Chilcott more than $100 million under the license included in the settlement. But they have pointed to no evidence that any of the parties to the 2006 Settlement expected that it would result in more than $100 million in payments. The settlement included a license providing for Bayer to pay royalties to Warner Chilcott.[320] These actual payments may have been entirely unexpected and a result of Yaz becoming more successful than anticipated. Moreover, any attempt to use the 2006 Settlement to support the validity of the '394 patent would be directly contrary to the language of the 2006 Settlement itself which explicitly states that [redacted].[321]

Finally, Defendants suggest that this settlement rebuts Purchasers' evidence that the '394 patent was fraudulently procured because Bayer never would have settled if there was fraud in the procurement of the patent.[322] However, such inferences are completely unwarranted because the 2006 settlement preceded any discovery that would have revealed the fraud to Bayer.[323] Such

[320] *See* Robertson Decl. Ex. O, Defs. Prelim. Ex. No. DX C-023 at § 4.2 [redacted].

[321] *See* Robertson Decl. Ex. O, Defs'. Prelim. Ex. No. DX C-023 at § 12.16 ("[redacted]").

[322] SJ Br. at 26 ("It is implausible to accept that a sophisticated pharmaceutical company like Bayer would have paid . . . for a license to an invalid patent.").

[323] SJ Opp. at 19-20 & n.119.

evidence is precisely the kind of unduly prejudicial evidence that should be excluded under Rule 403.[324]

Because the risk of confusion, prejudice, and delay from the introduction of other settlement agreements clearly outweighs any probative value that they may have, the use of any evidence of settlements to suggest the strength of the '394 patent should be excluded pursuant to Rule 403.

For the reasons set forth above, Purchasers respectfully request that the Court grant their motion *in limine* to exclude any evidence of settlements offered to prove the strength of the '394 patent.

### B. Motion No. 39: Purchasers' Motion *in Limine* to Preclude Defendants From Offering Argument or Evidence That Purchasers Were Not Injured or Did Not Suffer Damages Because, In the Absence of Defendants' Fraud on the Patent Office, Loestrin 24 Would Never Have Been Sold

Purchasers respectfully request an order precluding Defendants from offering evidence or argument to the jury that Purchasers have not suffered any injury or damages because, had there been no fraud on the United States Patent and Trademark Office, the '394 patent never would have issued, and Loestrin 24 would not have been developed and sold. This argument, which contravenes the antitrust law and misconstrues *Walker Process* fraud claims, should not be presented to the jury.

Defendants wish for a world in which "the more grievous the wrong done, the less likelihood there would be of a recovery."[325] The antitrust laws have squarely rejected such a

[324] *See McInnis*, 765 F.2d at 251-52 (finding trial court's admission of evidence of a settlement agreement prejudicial and noting "that it is doubtful that any instructions, no matter how clear and comprehensive, could eradicate the prejudice engendered by the admission of the release in this case").

[325] *See Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 265 (1946).

proposition. Instead, the antitrust laws instruct that Purchasers shall recover the "full amount of the overcharge" on the purchases they made at a price that was inflated by Defendants' unlawful conduct.[326] The measure of the overcharge is the difference between the actual price (*i.e.* the price reflecting the anticompetitive conduct) and the price Purchasers would have paid in the absence of the anticompetitive conduct, multiplied by the number of *actual purchases* Purchasers made at the inflated price.[327]

Purchasers are entitled to recover these overcharges on their actual purchases without being required to reconstruct each and every way the market may have hypothetically been different in the absence of Defendants' anticompetitive conduct.[328] Any uncertainty in how the market may have looked had Defendants not violated the law must be resolved in favor of Purchasers.[329]

Courts have routinely rejected arguments by antitrust defendants that purchaser damages should be reduced because those purchases may have been different in the but-for world where the

[326] *Illinois Brick*, 431 U.S. at 745-46.

[327] *See, e.g.*, Areeda & Hovenkamp, Antitrust Law ¶ 291e1 (2013) (recoverable overcharges are "the difference between the actual price and the 'but for' price . . . times *the quantity sold at the higher price*"); *see also* ABA Section of Antitrust Law, Proving Antitrust Damages: Legal and Economic Issues 233–34 (2d ed. 2010) (overcharges are "[t]he difference between the price charged and the competitive price . . . multiplied by *the quantity actually purchased*") (emphasis added)).

[328] *See Hanover Shoe*, 392 U.S. at 489; *see also In re Nexium Antitrust Litig.*, 777 F.3d 9, 27 (1st Cir. 2015).

[329] *Jay Edwards, Inc. v. New England Toyota Distrib., Inc.*, 708 F.2d 814, 821 (1st Cir. 1983) ("where the defendant's wrongdoing created the risk of uncertainty [in damages calculation], the defendant cannot complain about imprecision" (citing *Bigelow*, 327 U.S. 251)); *see also Va. Vermiculite, Ltd.* 156 F.3d at 540 ("even if Grace lawfully could have donated the lands to HGSI without the nonmining agreements, it is foreclosed from challenging causation simply on the basis that it could have achieved the same result through lawful means"); *Irvin Indus., Inc.*, 974 F.2d at 245 ("The possibility that [defendant] might have submitted a lawful bid, and, if so, the same damage might have resulted, cannot in and of itself negate causation as a matter of law"); *Lee-Moore Oil Co.*, 599 F.2d at 1302 ("the fact that [the defendant] might have caused the same damages by a lawful cancellation of the contract is irrelevant"); *In re Cardizem CD*, 105 F. Supp. 2d at 648 ("[t]o accept Defendants' argument, the Court must also accept the argument that there can never be an antitrust violation if the antitrust defendant can posit an argument that it could have lawfully done the same thing it is accused of doing collusively. The Court finds these arguments unavailing"), *aff'd*, 332 F.3d 896 (6th Cir. 2003).

defendant did not break the law.[330] Moreover, Defendants' argument that other cases are inapplicable because its alleged "lack of antitrust injury does not exist in most *Walker Process* fraud cases, where, unlike here, fraud is asserted for *follow-on* patents" is false.[331] Rather, *Walker Process* fraud cases involving only one patent, as here, have reached the same result.[332] As the Supreme Court cautioned in *Bigelow*, to hold otherwise "would be an inducement to make wrongdoing so effective and complete in every case as to preclude any recovery, by rendering the measure of damages uncertain."[333] Because the case law is clear that Defendants' argument that it would have not launched Loestrin 24 absent its fraud on the USPTO is irrelevant to the damages Defendants owe, allowing this testimony would also violate Federal Rule of Evidence 403.

Finally, Defendants' hypothetical Loestrin 24-free world wholly misconstrues the anticompetitive act committed in a *Walker Process* action. As this Court has recognized, "it is the *enforcement* of a patent procured by fraud that may give rise to a Sherman Act claim."[334] Here, the '394 patent *was actually procured*, Defendants *did actually sell* Loestrin 24, and Purchasers *did actually purchase* that Loestrin 24. The antitrust violation here occurred when Defendants asserted the fraudulently-procured '394 patent to prevent competition, thereby delaying the entry

[330] *See, e.g.*, *Relafen*, 346 F. Supp. 2d at 369-70 (noting "a substantial portion of the harm attributed to [the defendant's] conduct would go completely unredressed"); *Tawfillis v. Allergan, Inc.*, No. 8:15-cv-00307-JLS-JCG, 2017 WL 3084275, at *12 (C.D. Cal. June 26, 2017) (recognizing it "need not consider" what "could have affected the amount of the product purchased in the but-for world"); *Visa Check/Mastermoney*, 192 F.R.D. at 85 (rejecting hypothetical reduced volume of transactions as "immaterial"), *aff'd*, 280 F.3d 124 (2d Cir. 2001); *Skelaxin*, 2014 WL 2002887, at *5 ("courts and juries will not be forced down the rabbit hole of hypothetical issues antitrust violators may raise to minimize their liability").

[331] *See* Defs.' Rep. Mem. of Law in Support of Defs.' Mot. For Summ. J., at 3-4, ECF No. 1055.

[332] *See King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. at 410, 421 (E.D. Pa. 2015) (denying motion for summary judgment of lack of causation where the *Walker Process* claim alleged that, at the time of settlement, "Cephalon and the Generic Defendants knew that the RE '516 patent was invalid and unenforceable.").

[333] *Bigelow*, 327 U.S. at 264.

[334] *Loestrin*, 261 F. Supp. 3d at 339 (emphasis added).

of generic Loestrin 24 and forcing Purchasers to pay supracompetitive prices on their purchases of the drug.

Accordingly, the Court should preclude Defendants from suggesting that Purchasers should not recover because in the but-for world where the fraud on the PTO did not occur Purchasers would not have purchased Loestrin 24.

### C. Motion No. 40: Purchasers' Motion *in Limine* to Preclude Defendants from Offering Argument or Evidence About the Factual Record in Lawsuits Involving Different Parties and Different Drugs

Purchasers respectfully request an order precluding Defendants from offering argument or evidence about the factual record in lawsuits other than the Warner Chilcott/Watson infringement suit over the '394 patent regarding generic Loestrin 24. This would preclude speculative, hearsay argument and evidence about the actions in other lawsuits, regarding the presumed intentions of non-parties (e.g., Mylan, Lupin, Schering/Bayer), involving drugs other than Loestrin 24 (e.g., Yaz, LoLoestrin) (herein the "non-party litigation").

Based on evidence Defendants cited during summary judgment and placed on their exhibit list, Defendants may attempt to introduce speculative, hearsay evidence at trial that arguments made in lawsuits other than the Watson Loestrin 24 litigation, and the outcomes of those other litigations, provide evidence about the strength of the '394 patent. In their expert reports and summary judgment briefing and argument, defendants point to purported facts from other litigations involving the '394 patent for three reasons:

> (1) Because some generics did not allege inequitable conduct in later litigations, this shows that (a) there was no inequitable conduct, and, therefore, (b) Warner Chilcott's suit against Watson was not baseless;[335]

[335] Mem. of Law in Support of Defs.' Mot. for Sum. J. ("SJ Br."), ECF No. 858, at 4-5 ("Among the three patent infringement defendants (generics), two never alleged any form of inequitable conduct."); Reply Memorandum of Law in Support of Defendants' Motion for Summary Judgment ("Reply Br."), ECF No. 1055, at 4-5 ("In the real

(2) That Warner Chilcott "won" the claim construction in the later Mylan litigation shows that the human study and breakthrough bleeding are not material and thus no fraud occurred;[336]

(3) That the Schering suit ended with Schering paying for a license to the '394 patent means that Warner Chilcott's suit against Watson was not baseless.[337]

None of these purported facts are remotely admissible. Most are simply speculation driven by embedded hearsay about things that non-parties said and did in other litigation as proof about what the merits were of their situation, which "proof" is then offered for what would have occurred in the Warner Chilcott/Watson dispute years earlier.[338] The non-party litigation is not relevant to issues that the jury must decide in this antitrust case—speculation about non-party actions will confuse the jury by needlessly multiplying the number of litigations with which they must become familiar and blurring the line between evidence and litigation strategy that was, and was *not*, part of the Watson litigation—the only litigation that matters. Purchasers would be prejudiced under

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world, two generic firms (Lupin and Mylan) that litigated Loestrin 24 patent suits rejected the fraud on the PTO claims that Plaintiffs assert."); Defendants' slides re: *Walker Process* Fraud and Sham Litigation from summary judgment argument ("SJ Slides"), Sept. 11, 2019, ECF No. 1230, Ex. 11, at 2 ("Plaintiffs wholesale copy the Watson inequitable conduct arguments, but subsequent generics Lupin and Mylan elected not to make these arguments in patent court"), 26 ("the two generic firms sued by Chilcott in patent court after Watson did not include Watson's, or any other, inequitable conduct arguments in their defense" (emphasis in original), 66 (slide titled "Five '394 Patent Infringement Litigations—Only One Involved Allegations of Inequitable Conduct or *Walker Process* Fraud"); Defendants' Statements of Disputed Fact in Response to Plaintiffs' Additional Statement of Material Undisputed Facts ("Defs. SDF"), July 8, 2019, ECF No. 1054, ¶ 240 ("Indeed, in the Mylan and Lupin Loestrin 24 patent litigations, Mylan and Lupin did not allege any inequitable conduct or that the patent was unenforceable."); Expert Rept. of T. John Ward, Feb. 14, 2019, ECF No. 860-18, ¶¶ 141, 142, 227.

[336] SJ Br. 12 (Plaintiffs' assumption was expressly rejected by the district court [in the Mylan case], which held in its *Markman* opinion that 'a reduced incidence of breakthrough bleeding' was not a claim limitation in the '394 patent."); Reply Br. 5-6 (section titled "Warner Chilcott's Litigation Success: Judge Joel Pisano Accepted Warner Chilcott's Arguments and Bayer Took a License to the '394 Patent"); SJ Slides 42 (titled "30-Woman Study: Judge Pisano Rejected the Breakthrough Bleeding Argument in the Mylan *Markman* Hearing (D.N.J.)"), 65 ("Chilcott won the *Markman* ruling in the Mylan action."); ECF No. 860-18 ¶ 153-155.

[337] SJ Br., 21 ("The undisputed, objective facts establish the strength of the '394 patent, including that (1) in response to Warner's 2006 lawsuit against Schering AG for Yaz's infringement of the '394 patent, Schering (now Bayer) agreed to settle rather than litigate . . ."); Reply Br., 19 ("Nor can Plaintiffs escape the fact of the 2006 Yaz license to Bayer"); ECF No. 860-18 ¶¶ 145-147.

[338] Fed. R. Evid. 801 ("'Hearsay' means a statement that: (1) the declarant does not make while testifying at the current trial or hearing; and (2) a party offers in evidence to prove the truth of the matter asserted in the statement.").

Fed. R. Evid. 403 by being bound to not only a court decision but by *litigation strategies* in actions to which neither Purchasers nor Watson was a party. To allow such evidence would essentially foist upon Purchasers a black box of litigation strategies of other parties in other litigations—strategies that would be subject to attorney-client privilege even if discovery regarding those decisions had been taken. Further, as discussed in depth in Purchasers' Motion *in Limine* No. 37, evidence related to other settlements should be excluded under Federal Rule of Evidence 403 because they are not relevant to the case at issue and any probative value would be substantially outweighed by the danger of confusion, prejudice, undue delay, and waste of time.

Even if the Court were to give limiting instructions on these issues, the jury could be confused and may not understand the actual evidentiary value of what occurred in these other cases. "Curative instructions are not fool-proof."[339] For these and the reasons discussed below, Defendants' arguments and evidence regarding the three issues from other litigations should be excluded under Rules 401, 402, and 403 of the Federal Rules of Evidence.

**1. Defendants should be precluded from introducing argument or evidence regarding whether other parties asserted inequitable conduct defenses in unrelated patent litigation.**

Defendants argue in their summary judgment briefing that Purchasers' fraud claims are defeated because "two generic firms (Lupin and Mylan) that litigated the Loestrin 24 patent suits rejected the fraud on the PTO claims."[340] Defendants have a similar argument regarding Watson's choice not to assert inequitable conduct claims regarding the '394 patent in litigation involving the Lo Loestrin product.[341]

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[339] *See Blue Cross & Blue Shield of New Jersey, Inc. v. Philip Morris, Inc.*, 138 F. Supp. 2d 357, 370-71 (E.D.N.Y. 2001).

[340] *See supra* note 335.

[341] *Id.*

The fact that later litigants chose not to assert inequitable conduct claims, however, is not relevant to any issue in this case. Evidence is relevant if "(a) it has any tendency to make a fact more or less probable that it would be without the evidence, and (b) the fact is of consequence in determining the action."[342] Here, however, whether parties to unrelated cases pursued inequitable conduct defenses regarding the '394 patent does not tend to make any fact more or less probable. Whether Lupin, Mylan, or Watson in the Lo Loestrin case asserted inequitable conduct claims in their litigation is irrelevant both to what Warner Chilcott believed to be the strength of the '394 patent when it settled with Watson in the case at issue here and to the likelihood that Watson would win its inequitable conduct claim. In fact, evidence of the actions of other unrelated parties in unrelated cases would be highly prejudicial to Purchasers.[343]

*Other Parties' Litigation Strategies Are Irrelevant & Speculative Hearsay:* First, some version of the following three questions will be put to the jury in this case:

> (1) Whether the patent had been obtained by fraud, and whether Warner Chilcott knew that when it sued *Watson*;[344]
>
> (2) Whether a reasonable pharmaceutical manufacturer in Warner Chilcott's position would realistically expect to prove that *Watson* infringed a valid patent;[345] and

[342] Fed. R. Evid. 401.

[343] *See, e.g., CPC Intern., Inc. v. Northbrook Excess and Surplus Ins. Co.*, 144 F.3d 35, 44-45 (1st Cir. 1998) (upholding district court's exclusion of judicial decisions in previous insurance coverage suits by insured involving groundwater contamination at its facilities); *Mendenhall v. Cedarapids, Inc.*, 5 F.3d 1557, 1573-75 (Fed. Cir. 1995) (upholding the exclusion of prior adjudications on the grounds such information was prejudicial under Rule 403 and there was no evidence that it was relevant and probative); *Lemelson v. General Mills, Inc.*, No. 77 C 4558, 1987 WL 12999, at *3 (N.D. Ill. June 19, 1987) (refusing to admit evidence of reissue proceedings and subsequent litigation under Rule 403). In *Mendenhall*, the Federal Circuit also held that the trial record from a prior adjudication was inadmissible hearsay. *Mendenhall*, 5 F.3d at 1571.

[344] *See, e.g., Tyco Healthcare Group LP v. Mutual Pharmaceutical Co.*, 762 F.3d 1338, 1349 (Fed. Cir. 2014); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071 (Fed. Cir. 1998); *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 692 (2d Cir. 2009).

[345] *See, e.g., Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993).

(3) Whether Warner Chilcott made a large and unjustifiable payment to *Watson* in exchange for *Watson's* delayed launch.[346]

Whether Mylan, Lupin, or Watson in unrelated cases brought inequitable conduct claims regarding the '394 patent is irrelevant to answering any of these questions. The jury must focus on the record in the Watson litigation, Watson and Warner Chilcott's views, and whether Watson developed evidence that would support its fraud claim. Watson *did* allege inequitable conduct in its litigation with Warner Chilcott over Loestrin 24 Fe. As defendants repeatedly note, those allegations have greatly informed the allegations of Purchasers in this case.[347] Watson *did* adduce evidence to support its inequitable conduct theory; much of this same evidence is encapsulated in the antitrust Purchasers' summary judgment record. Facts about later litigations cannot speak to whether Watson met its burden of proving fraud. Only the evidence from the Watson litigation can inform the jury on these points. Information about later litigations cannot speak to these issues. Defendants cannot point to the *absence* of a record of *other* factfinders deciding these issues to supplant the jury's factfinding responsibilities in this case.[348]

*No Court Has Ever Ruled on the Merits of the '394 Patent:* Second, no court—not the court in the Watson Loestrin 24 litigation nor any other court—ever decided the validity or enforceability of the '394 patent on the merits. Warner Chilcott avoids this inconvenient fact and harps instead on what various parties alleged or did not allege.

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[346] *FTC v. Actavis, Inc.*, 570 U.S. at 158. This question implicates the '394 patent because plaintiffs economics expert Thomas McGuire uses, as an input, the likelihood of Watson winning the patent infringement litigation in assessing the size and effect of the payment. Expert Rept. of Thomas G. McGuire, Jan. 4, 2019, ECF No. 877-13, ¶¶ 214-24.

[347] *See supra* note 335.

[348] *Mendenhall v. Cedarapids, Inc.*, 5 F.3d at 1574 (precluding the admission of an opinion in an unrelated case because it would impermissibly "influence the jury's fact finding mission").

*Other Parties' Litigation Strategies Are Unknowable Here:* Third, even if the litigation strategy choices of other parties were relevant, evidence and argument about those choices is highly prejudicial because there is no way for the parties to understand *why* those choices were made. Warner Chilcott offers *no evidence* as to *why* other generics did not allege inequitable conduct. Defendants simply speculate—with zero evidentiary support—that it may have been due to change in the inequitable conduct law, or it may have been because they did not think that fraud had been committed under any standard. There are other reasons than perceived strength of argument that could affect a party's choice not to pursue certain claims. For example, as later filers who would not have exclusivity like Watson did, Mylan and Lupin may have been "motivated by practical trial strategy and its dim prospects for obtaining first filer status," as Judge Douglas Miller noted in another antitrust case involving a similar argument about the choice of a later generic not to assert inequitable conduct.[349] Defendants' rank speculation cannot stand, particularly not when it accompanies significant Rule 403 prejudice that the jury might actually think that the strategy choices of others have bearing on the expected outcome of the Watson litigation. "There is no exemption from Rule 403 for evidence of prior litigation."[350] Without any actual evidence about why such litigation strategy choices were made, jurors may give improper deference to choices and decisions from another case.[351]

*Other Parties' Views Are Irrelevant to the Issues of this Case:* Fourth, as to the second patent-related jury question above, relating to sham litigation, Defendants argue that because other

[349] *In re Zetia (Ezetimibe) Antitrust Litig.*, 2:18-md-0286-RBS-DEM (E.D. Va.), ECF No. 234, Magistrate Judge's Report and Recommendation (Feb. 26, 2019) at 47, *adopted at* ECF No. 489, Opinion (August 9, 2019).

[350] *Mendenhall*, 5 F.3d at 1573.

[351] *See Lemelson*, 1987 WL 12999, at *3 (excluding evidence from other cases involving the same patent because the jury may give "improper deference" to the decision from another case and because "prior adjudication may be misunderstood in its scope by the jury and deemed controlling").

generics did not argue fraud, that means that the litigation could not have been baseless. But Watson also adduced evidence that—even if the PTO had not been intentionally defrauded—that patent was invalid as obvious. Further, as Purchasers' patent expert Edward Lentz has opined in this case, the Watson record supports the conclusion that Watson had a 90% chance of winning the patent litigation, either because the patent was obtained by fraud (and Warner Chilcott knew it) or because the patent was invalid.[352] In other words, even if there were no inequitable conduct, Watson would still have won the litigation because the patent was obvious. Therefore, facts about whether others alleged fraud have no bearing on whether the litigation was a sham.

Fifth, as to the third question regarding the settlement, what is relevant is what the views of the parties—Warner Chilcott and Watson—were when they sat down at the settlement table. Or, in the absence of evidence of their views (e.g., if they are withheld as privileged, as they have been here), evidence about discovery taken, arguments made, and the facts on the ground in the Watson litigation at the time of settlement. As this Court has observed, "every case has to be evaluated on its own merits."[353] It is the state-of-play at the time of settlement that matters, not what happened years later.

*Collateral Estoppel Does Not Apply:* Sixth, it is well established that "A plaintiff cannot be collaterally estopped by an earlier determination in a case in which the plaintiff was neither a party nor in privity with a party."[354] How then can a party be bound by the decision *not to assert a claim* in an unrelated lawsuit? Which theories other generic companies did and did not press in

[352] Expert Rept. of Edward T. Lentz, Jan. 4, 2019, ECF No. 953-6, ¶ 290.

[353] Robertson Decl. Ex. I at 55:4-7.

[354] *Gen. Elec. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1083 (7th Cir. 1997). *See also In re Lipitor Antitrust Litig.*, 868 F.3d 231, 267 (3d Cir. 2017) (holding that plaintiffs could not be estopped from asserting *Walker Process* fraud because of factual resolution of issues in prior litigation when they were not parties to that litigation).

litigation occurring after the Watson litigation at issue here, and why they made the choices they made, is simply irrelevant to whether Watson would have prevailed in an earlier suit.

**2. Defendants should be precluded from introducing evidence or argument that Warner Chilcott "won" or "prevailed" in the claim construction opinion in the Mylan litigation.**

Defendants have argued in their summary judgment briefing that Warner Chilcott "won" the claim construction opinion that the court issued in the Mylan litigation is objective evidence that Warner Chilcott's suit against Watson was not baseless.[355]

First, this interpretation of the claim construction decision is incorrect, and it would be highly prejudicial for defendants to use terms such as "won" or "prevailed in" with regards to that opinion.[356] A jury could be prejudicially confused or mislead if defendants were permitted to argue that Warner Chilcott "won" the Mylan claim construction.[357]

Second, Warner Chilcott is functionally asking for collateral estoppel on this issue. It is asking this Court (at summary judgment) and the jury (at trial) to import (1) the Mylan court's conclusion that "a reduction in the incidence of breakthrough bleeding" is not a claim limitation and (2) a statement by the Mylan court that, out of context, can be read to suggest that the human study and breakthrough bleeding information are not material to patentability.[358] However, collateral estoppel does not apply here. "[I]f a court could take judicial notice of a fact simply because it was found to be true in a previous action, the doctrine of collateral estoppel would be superfluous. A plaintiff cannot be collaterally estopped by an earlier determination in a case in

[355] SJ Br. at 21-22; Slides, 65.

[356] This Court previously chose not to take judicial notice of the claim construction opinion. *Loestrin*, 261 F. Supp. 3d at 343.

[357] Fed. R. Evid. 403.

[358] *See supra* note 355.

which the plaintiff was neither a party nor in privity with a party."[359] In generic delay antitrust cases, courts routinely reject such back-door collateral estoppel efforts.[360]

**3. Defendants should be precluded from introducing argument or evidence that the settlement reached in the Yaz Litigation is evidence of the strength of the '394 Patent.**

As discussed at length in Purchasers' Motion *in Limine* No. 37, Defendants should also be precluded from introducing evidence or argument that the 2006 settlement of patent litigation by Bayer concerning its Yaz contraceptive is evidence of the strength of the '394 patent. Further, as discussed above, the specifics of other litigations and the particular choices made by the litigants in those cases are irrelevant to any of the issues in this case. For these reasons, Purchasers request that defendants be precluded from offering argument or evidence about the Yaz settlement deal, the Yaz license, or any money Bayer allegedly paid for that license.

**D. Motion No. 41: Purchasers' Motion *in Limine* to Exclude Evidence and Argument Regarding the "Materiality" or "Novelty" of Inventions or Prior Art References from Witnesses Not Qualified as Experts in Patent Laws**

Purchasers respectfully request an order precluding Defendants from introducing evidence or argument—other than from a witness qualified as an expert capable of opining on materiality or novelty—that any alleged invention or prior art reference is "material" or "novel," as these words have a special meaning within patent law that could be confusing to a jury if used in a different context.

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[359] *Gen. Elec. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1083 (7th Cir. 1997) (citations omitted).

[360] *See also Lipitor*, 868 F.3d at 267 (holding that plaintiffs could not be estopped from asserting *Walker Process* fraud because of factual resolution of issues in prior litigation when they were not parties to that litigation); *In re Zetia (Ezetimibe) Antitrust Litig.*, 2:18-md-0286-RBS-DEM (E.D. Va.), ECF No. 234, Magistrate Judge's Report and Recommendation (Feb. 26, 2019) at 47 (holding that failure by other parties to assert an inequitable conduct claim was no reason to dismiss antitrust plaintiffs' fraud claims), *adopted at* ECF No. 489, Op. (August 9, 2019).

The terms "material" and "novel" have dual meanings: both an ordinary, everyday meaning and a special meaning under patent law. The jury will undoubtedly be instructed on the definition of "material" under patent law, as materiality is an element of patent fraud. In Defendants' expert reports, summary judgment briefing, and arguments to this Court, they have used these terms ambiguously. Sometimes it is impossible to tell which sense of the word they intend. Defendants should not be permitted to sew such confusion. Purchasers therefore respectfully request that Defendants be precluded from introducing evidence, testimony, or argument that uses the terms "material," "novel," or other terms with special meaning under patent law in their ordinary sense.[361] In the alternative, Defendants' experts without patent law background or training ought to be precluded from using these terms in their ordinary sense, and Defendants' lay witnesses ought to be precluded from using these terms as doing so would constitute impermissible lay opinion testimony under Federal Rule of Evidence 701. Additionally, such testimony would also violate Federal Rule of Evidence 702 if that expert does not possess the scientific, technical or other specialized knowledge to render an opinion about the patents at issue.[362]

[361] *See Burkhart*, 112 F.3d at 1213 (holding that the trial court erred in failing to exclude expert testimony that an officer's communications with Plaintiff "were not 'as effective' as the means of communications with others" where the expert "misstated the law as to what constitutes 'as effective' communication with the disabled" and "[t]he phrase 'as effective' is lifted directly from the text of the Attorney General's regulations implementing the ADA [and] the phrase as used in the regulations is a term of art with a meaning 'separate' and 'distinct' from the vernacular."); *Forsythe v. Rosen Med. Grp., LLC*, No. 11-cv-07676, 2015 WL 127921, at *4 (N.D. Ill. Jan. 8, 2015) (granting motion *in limine* prohibiting Plaintiffs from referring to Defendant Surgeons using the colloquial phrase "Captains of the Ship" because this phrase could confuse the jury as to the application of the "captain of the ship" legal doctrine); *EEOC v. Dial Corp*., 99-cv-3356, 2002 WL 31061088, at *4 (N.D. Ill. Sept. 17, 2002) (granting motion *in limine* in relevant part prohibiting expert testimony of SEQ that defined sexual harassment differently than its legal meaning, and holding that "[a]lthough it is possible to define sexual harassment in its legal and its social science or non-legal meaning, the risk of the jury's failure to keep the distinction always in mind diminishes the usefulness of testimony and a survey built upon the non-legal definition. That is particularly true during a lengthy trial, which this one promises to be.").

[362] Purchasers have separately challenged Dr. Darney's ability to offer conclusions about materiality, in either sense of the word, given his lack of qualifications and/or lack of instruction on patent law meaning of the term. ECF No. 922.

As Defendants have acknowledged, "[t]o sustain an antitrust claim that the '394 patent was obtained by fraud, Purchasers must prove that . . . the patentee (1) made a ***material*** misrepresentation or omission of fact . . . ."[363] Defendants have further recognized that, under the patent laws, "'[m]aterial' means 'the patent would not have issued but for the misrepresentation or omission.'"[364] The First Circuit has acknowledged that this "materiality requirement is a meaningful one."[365] Because a key issue in this case is whether or not certain publications and uses withheld from the PTO during prosecution of the '394 patent were ***material***—in the patent law sense of the word, using "material" in a more colloquial sense is likely to confuse the jury. Specifically, jurors may have difficulty discerning when evidence or argument using the word "material" is directed to the type of materiality defined by the patent laws. For example, if a medical expert were to testify that a study or reference would not have been material to their practice, the witness might mean that they would not have changed their prescribing practices based on the reference. But the jury might interpret this testimony to mean that the reference is not material in the patent law sense—which is not what the witness meant. As such, if a witness is not qualified as an expert in patent law, and so qualified to offer an opinion on materiality in the patent law sense—which "is analyzed from the perspective of the PTO"—they should be excluded from using the term "material" in order to avoid confusing the jury and prejudicing Purchasers who must prove patent law materiality. [366]

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[363] SJ Br., ECF No. 858 at 7 (emphasis added).

[364] *Id.* (citing *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070 (Fed. Cir. 1998)).

[365] *Id.* (citing *United Food & Comm. Workers Unions & Emp's Midwest Health Benefits Fund v. Novartis Pharm. Corp.*, 902 F.3d 1, 9 (1st Cir. 2018)).

[366] *Aevoe Corp. v. AE Tech Co., Ltd.*, No. 12-cv-0053, 2014 WL 4182343, at *2 (D. Nev. Aug. 20, 2014) (citing *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1345 (Fed. Cir. 2013)); *see also Ohio Willow Wood Co.*, 735 F.3d at 1333 ("[T]he analysis of this *but-for* materiality requirement is from the perspective of the PTO.").

Similarly, the Supreme Court has recognized that the patent statute "is split into two sections, section 101 relating to the subject matter for which patents may be obtained, and ***section 102 defining statutory novelty*** and stating other conditions for patentability."[367] Section 102 defines novelty and prior art by stating that "[a] person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention . . . ."[368] Defendants acknowledge that one of the key issues in this case is whether "the 30-Woman Study is an invalidating ***public use*** that should have been disclosed to the PTO."[369] Because section 102 defines a prior public use as novelty-destroying, one of the central issues in this case is whether the alleged invention claimed in the '394 patent is novel, as defined by 35 U.S.C. § 102. As with materiality, this means that using "novel" in a more colloquial sense is likely to confuse the jury. Specifically, jurors may have difficulty discerning when evidence or argument using the word "novel" is directed to the type of novelty that is specially defined by section 102. For example, if a witness were to testify that "Loestrin 24 is the product of a novel invention," as Defendants state in their Summary Judgment Briefing, the witness might mean that Loestrin 24 was a drug that had never been on the market before in its current form. But the jury might interpret this as testimony that, in the witness's opinion, the '394 patent that covers Loestrin 24 meets the novelty requirement for patentability—which is not what the witness meant. For this reason, if a witness is not qualified as an expert to opine on novelty in the patent law sense, that witness should be excluded from using the term "novel" in order to avoid confusing the jury and prejudicing the Purchasers who

[367] *Diamond v. Diehr*, 450 U.S. 175, 190 (1981) (quoting S. Rep. No. 1979, 82d Cong., 2d Sess., 17 (1952), U.S. Code Cong. & Admin. News, 1952, p. 2409) (emphasis added)).

[368] 35 U.S.C. § 102(a)(1).

[369] SJ Br., ECF No. 858 at 13 (emphasis added).

must prove, *inter alia*, that certain references or public uses were novelty-destroying as to the '394 patent.

For the foregoing reasons, the Court should exclude any evidence or argument, other than from a witness qualified as an expert to opine on materiality or novelty in the context of patent law, that any alleged invention or prior art reference is "material" or "novel."

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Sharon K. Robertson, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's CM/ECF system. Those attorneys who are registered CM/ECF users may access these filings, and notice of these filings will be sent to those parties by operation of the CM/ECF system.

Dated: October 24, 2019

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